

108TH CONGRESS
1ST SESSION

S. 7

To amend title XVIII of the Social Security Act to provide coverage of outpatient prescription drugs under the medicare program and to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JANUARY 7, 2003

Mr. DASCHLE (for himself, Mr. ROCKEFELLER, Ms. STABENOW, Mr. SCHUMER, Mr. KENNEDY, Mrs. CLINTON, Mr. AKAKA, Mr. CORZINE, Mr. DURBIN, Ms. MIKULSKI, Mr. LEAHY, Mr. LEVIN, Mr. JOHNSON, Mr. REED, Mr. SARBANES, Mr. DAYTON, Mr. LAUTENBERG, and Mr. REID) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend title XVIII of the Social Security Act to provide coverage of outpatient prescription drugs under the medicare program and to amend the Federal Food, Drug, and Cosmetic Act to provide greater access to affordable pharmaceuticals, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) SHORT TITLE.—This title may be cited as the
 3 “Prescription Drug Benefit and Cost Containment Act of
 4 2003”.

5 (b) TABLE OF CONTENTS.—The table of contents of
 6 this title is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Findings.

**TITLE I—MEDICARE OUTPATIENT PRESCRIPTION DRUG BENEFIT
PROGRAM**

Sec. 101. Medicare outpatient prescription drug benefit program.

“PART D—OUTPATIENT PRESCRIPTION DRUG BENEFIT PROGRAM

“Sec. 1860. Definitions.

“Sec. 1860A. Establishment of outpatient prescription drug benefit program.

“Sec. 1860B. Enrollment under program.

“Sec. 1860C. Enrollment in a plan.

“Sec. 1860D. Providing information to beneficiaries.

“Sec. 1860E. Premiums.

“Sec. 1860F. Outpatient prescription drug benefits.

“Sec. 1860G. Entities eligible to provide outpatient drug benefit.

“Sec. 1860H. Minimum standards for eligible entities.

“Sec. 1860I. Payments.

“Sec. 1860J. Employer incentive program for employment-based retiree drug
coverage.

“Sec. 1860K. Prescription Drug Account in the Federal Supplementary Med-
ical Insurance Trust Fund.

“Sec. 1860L. Medicare Prescription Drug Advisory Committee.”.

Sec. 102. Part D benefits under Medicare+Choice plans.

Sec. 103. Additional assistance for low-income beneficiaries.

Sec. 104. Medigap revisions.

Sec. 105. Coverage of immunosuppressive drugs for all medicare beneficiaries
under part B.

Sec. 106. HHS study and report on uniform pharmacy benefit cards.

Sec. 107. Expansion of membership and duties of Medicare Payment Advisory
Commission (MedPAC).

**TITLE II—PRESCRIPTION DRUG COST CONTAINMENT AND
QUALITY ASSURANCE**

Sec. 201. Filing of patent information with the Food and Drug Administration.

Sec. 202. Limitation of 30-month stay to certain patents.

Sec. 203. Exclusivity for accelerated generic drug applicants.

Sec. 204. Fair treatment for innovators.

Sec. 205. Bioequivalence.

Sec. 206. Clarification of State authority relating to medicaid drug rebate
agreements.

Sec. 207. Importation of prescription drugs.
 Sec. 208. Pediatric labeling of drugs and biological products.
 Sec. 209. Report.
 Sec. 210. Conforming and technical amendments.

1 **SEC. 2. FINDINGS.**

2 Congress makes the following findings:

3 (1) Prescription drug coverage was not a stand-
 4 ard part of health insurance when the medicare pro-
 5 gram under title XVIII of the Social Security Act
 6 was enacted in 1965. Since 1965, however, drug cov-
 7 erage has become a key component of most private
 8 and public health insurance coverage, except for the
 9 medicare program.

10 (2) At least $\frac{2}{3}$ of medicare beneficiaries have
 11 unreliable, inadequate, or no drug coverage at all.

12 (3) Seniors who do not have drug coverage typi-
 13 cally pay 15 percent more for prescription drugs
 14 than individuals who have such coverage.

15 (4) The number of private firms offering retiree
 16 health coverage is declining.

17 (5) The premiums for medicare supplemental
 18 policies (medigap policies) that provide prescription
 19 drug coverage are too expensive for most medicare
 20 beneficiaries and are highest for older senior citizens
 21 who need prescription drug coverage the most and
 22 typically have the lowest incomes.

1 (6) All medicare beneficiaries should have ac-
2 cess to a voluntary, reliable, affordable outpatient
3 drug benefit as part of the medicare program that
4 assists with the high cost of prescription drugs and
5 protects them against excessive out-of-pocket costs.

6 (7) Generic pharmaceuticals are approved by
7 the Food and Drug Administration on the basis of
8 scientific testing and other information establishing
9 that pharmaceuticals are therapeutically equivalent
10 to brand-name pharmaceuticals, ensuring consumers
11 a safe, efficacious, and cost-effective alternative to
12 brand-name innovator pharmaceuticals.

13 (8) The Congressional Budget Office estimates
14 that—

15 (A) the use of generic pharmaceuticals for
16 brand-name pharmaceuticals could save pur-
17 chasers of pharmaceuticals between
18 \$8,000,000,000 and \$10,000,000,000 each
19 year; and

20 (B) generic pharmaceuticals cost between
21 25 percent and 60 percent less than brand-
22 name pharmaceuticals, resulting in an esti-
23 mated average savings of \$15 to \$30 on each
24 prescription.

5 **TITLE I—MEDICARE OUT-**
6 **PATIENT PRESCRIPTION**
7 **DRUG BENEFIT PROGRAM**

8 SEC. 101. MEDICARE OUTPATIENT PRESCRIPTION DRUG
9 BENEFIT PROGRAM.

(a) ESTABLISHMENT.—Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) is amended by redesignating part D as part E and by inserting after part C the following new part:

14 “PART D—OUTPATIENT PRESCRIPTION DRUG BENEFIT
15 PROGRAM

16 “DEFINITIONS

17 “SEC. 1860. In this part:

18 “(1) COVERED OUTPATIENT DRUG.—

19 “(A) IN GENERAL.—Except as provided in
20 subparagraph (B), the term ‘covered outpatient
21 drug’ means any of the following products:

22 “(i) A drug which may be dispensed
23 only upon prescription, and—

24 “(I) which is approved for safety
25 and effectiveness as a prescription

1 drug under section 505 of the Federal
2 Food, Drug, and Cosmetic Act;

3 “(II)(aa) which was commercially
4 used or sold in the United States be-
5 fore the date of enactment of the
6 Drug Amendments of 1962 or which
7 is identical, similar, or related (within
8 the meaning of section 310.6(b)(1) of
9 title 21 of the Code of Federal Regu-
10 lations) to such a drug, and (bb)
11 which has not been the subject of a
12 final determination by the Secretary
13 that it is a ‘new drug’ (within the
14 meaning of section 201(p) of the Fed-
15 eral Food, Drug, and Cosmetic Act)
16 or an action brought by the Secretary
17 under section 301, 302(a), or 304(a)
18 of such Act to enforce section 502(f)
19 or 505(a) of such Act; or

20 “(III)(aa) which is described in
21 section 107(c)(3) of the Drug Amend-
22 ments of 1962 and for which the Sec-
23 retary has determined there is a com-
24 pelling justification for its medical
25 need, or is identical, similar, or re-

lated (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (bb) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for all conditions of use prescribed, recommended, or suggested in its labeling.

“(ii) A biological product which—

“(I) may only be dispensed upon prescription;

“(II) is licensed under section 351 of the Public Health Service Act; and

“(III) is produced at an establishment licensed under such section to produce such product.

1 “(iii) Insulin approved under appro-
 2 priate Federal law, including needles and
 3 syringes for the administration of such in-
 4 sulin.

5 “(iv) A prescribed drug or biological
 6 product that would meet the requirements
 7 of clause (i) or (ii) except that it is avail-
 8 able over-the-counter in addition to being
 9 available upon prescription.

10 “(B) EXCLUSION.—The term ‘covered out-
 11 patient drug’ does not include any product—

12 “(i) except as provided in subpara-
 13 graph (A)(iv), which may be distributed to
 14 individuals without a prescription;

15 “(ii) for which payment is available
 16 under part A or B or would be available
 17 under part B but for the application of a
 18 deductible under such part (unless pay-
 19 ment for such product is not available be-
 20 cause benefits under part A or B have
 21 been exhausted), determined, except as
 22 provided in subparagraph (C), without re-
 23 gard to whether the beneficiary involved is
 24 entitled to benefits under part A or en-
 25 rolled under part B; or

1 “(iii) except for agents used to pro-
2 mote smoking cessation and agents used
3 for the treatment of obesity, for which cov-
4 erage may be excluded or restricted under
5 section 1927(d)(2).

6 “(2) ELIGIBLE BENEFICIARY.—The term ‘eligi-
7 ble beneficiary’ means an individual that is entitled
8 to benefits under part A or enrolled under part B.

9 “(3) ELIGIBLE ENTITY.—The term ‘eligible en-
10 tity’ means any entity that the Secretary determines
11 to be appropriate to provide eligible beneficiaries
12 with covered outpatient drugs under a plan under
13 this part, including—

14 “(A) a pharmacy benefit management com-
15 pany;

16 “(B) a retail pharmacy delivery system;

17 “(C) a health plan or insurer;

18 “(D) a State (through mechanisms estab-
19 lished under a State plan under title XIX or
20 under a State pharmaceutical assistance pro-
21 gram);

22 “(E) any other entity approved by the Sec-
23 retary; or

1 “(F) any combination of the entities de-
 2 scribed in subparagraphs (A) through (E) if the
 3 Secretary determines that such combination—

4 “(i) increases the scope or efficiency
 5 of the provision of benefits under this part;
 6 and

7 “(ii) is not anticompetitive.

8 “(4) MEDICARE+CHOICE ORGANIZATION;
 9 MEDICARE+CHOICE PLAN.—The terms
 10 ‘Medicare+Choice organization’ and
 11 ‘Medicare+Choice plan’ have the meanings given
 12 such terms in subsections (a)(1) and (b)(1), respec-
 13 tively, of section 1859 (relating to definitions relat-
 14 ing to Medicare+Choice organizations).

15 “(5) PRESCRIPTION DRUG ACCOUNT.—The
 16 term ‘Prescription Drug Account’ means the Pre-
 17 scription Drug Account (as established under section
 18 1860K) in the Federal Supplementary Medical In-
 19 surance Trust Fund under section 1841.

20 “ESTABLISHMENT OF OUTPATIENT PRESCRIPTION DRUG
 21 BENEFIT PROGRAM

22 “SEC. 1860A. (a) PROVISION OF BENEFIT.—

23 “(1) IN GENERAL.—As soon as the Prescription
 24 Drug Benefit and Cost Containment Act of 2003
 25 can be implemented after the date of enactment of
 26 that Act, the Secretary shall provide for and admin-

1 ister an outpatient prescription drug benefit pro-
 2 gram under which each eligible beneficiary enrolled
 3 under this part shall be provided with coverage of
 4 covered outpatient drugs as follows:

5 “(A) MEDICARE+CHOICE PLAN.—If the el-
 6 igible beneficiary is eligible to enroll in a
 7 Medicare+Choice plan, the beneficiary—

8 “(i) may enroll in such a plan; and

9 “(ii) if so enrolled, shall obtain cov-
 10 erage of covered outpatient drugs through
 11 such plan.

12 “(B) MEDICARE PRESCRIPTION DRUG
 13 PLAN.—If the eligible beneficiary is not enrolled
 14 in a Medicare+Choice plan, the beneficiary
 15 shall obtain coverage of covered outpatient
 16 drugs through enrollment in a plan offered by
 17 an eligible entity with a contract under this
 18 part.

19 “(2) VOLUNTARY NATURE OF PROGRAM.—
 20 Nothing in this part shall be construed as requiring
 21 an eligible beneficiary to enroll in the program es-
 22 tablished under this part.

23 “(3) SCOPE OF BENEFITS.—The program es-
 24 tablished under this part shall provide for coverage

1 of all therapeutic classes of covered outpatient
2 drugs.

3 “(b) ACCESS TO ALTERNATIVE PRESCRIPTION DRUG
4 COVERAGE.—In the case of an eligible beneficiary who has
5 creditable prescription drug coverage (as defined in section
6 1860B(b)(1)(F)), such beneficiary—

7 “(1) may continue to receive such coverage and
8 not enroll under this part; and

9 “(2) pursuant to section 1860B(b)(1)(C), is
10 permitted to subsequently enroll under this part
11 without any penalty and obtain coverage of covered
12 outpatient drugs in the manner described in sub-
13 section (a) if the beneficiary involuntarily loses such
14 coverage.

15 “(c) FINANCING.—The costs of providing benefits
16 under this part shall be payable from the Prescription
17 Drug Account.

18 “ENROLLMENT UNDER PROGRAM

19 “SEC. 1860B. (a) ESTABLISHMENT OF PROCESS.—

20 “(1) PROCESS SIMILAR TO ENROLLMENT
21 UNDER PART B.—The Secretary shall establish a
22 process through which an eligible beneficiary (includ-
23 ing an eligible beneficiary enrolled in a
24 Medicare+Choice plan offered by a
25 Medicare+Choice organization) may make an elec-
26 tion to enroll under this part. Such process shall be

1 similar to the process for enrollment in part B under
 2 section 1837, including the deeming provisions of
 3 such section.

4 “(2) REQUIREMENT OF ENROLLMENT.—An eli-
 5 gible beneficiary must enroll under this part in order
 6 to be eligible to receive covered outpatient drugs
 7 under this title.

8 “(b) SPECIAL ENROLLMENT PROCEDURES.—

9 “(1) LATE ENROLLMENT PENALTY.—

10 “(A) INCREASE IN PREMIUM.—Subject to
 11 the succeeding provisions of this paragraph, in
 12 the case of an eligible beneficiary whose cov-
 13 erage period under this part began pursuant to
 14 an enrollment after the beneficiary’s initial en-
 15 rollment period under part B (determined pur-
 16 suant to section 1837(d)) and not pursuant to
 17 the open enrollment period described in para-
 18 graph (2), the Secretary shall establish proce-
 19 dures for increasing the amount of the monthly
 20 part D premium under section 1860E(a) appli-
 21 cable to such beneficiary by an amount that the
 22 Secretary determines is actuarially sound for
 23 each full 12-month period (in the same contin-
 24 uous period of eligibility) in which the eligible

1 beneficiary could have been enrolled under this
 2 part but was not so enrolled.

3 “(B) PERIODS TAKEN INTO ACCOUNT.—
 4 For purposes of calculating any 12-month pe-
 5 riod under subparagraph (A), there shall be
 6 taken into account—

7 “(i) the months which elapsed be-
 8 tween the close of the eligible beneficiary’s
 9 initial enrollment period and the close of
 10 the enrollment period in which the bene-
 11 ficiary enrolled; and

12 “(ii) in the case of an eligible bene-
 13 ficiary who reenrolls under this part, the
 14 months which elapsed between the date of
 15 termination of a previous coverage period
 16 and the close of the enrollment period in
 17 which the beneficiary reenrolled.

18 “(C) PERIODS NOT TAKEN INTO AC-
 19 COUNT.—

20 “(i) IN GENERAL.—For purposes of
 21 calculating any 12-month period under
 22 subparagraph (A), subject to clause (ii),
 23 there shall not be taken into account
 24 months for which the eligible beneficiary
 25 can demonstrate that the beneficiary had

1 creditable prescription drug coverage (as
2 defined in subparagraph (F)).

3 “(ii) APPLICATION.—This subpara-
4 graph shall only apply with respect to a
5 coverage period the enrollment for which
6 occurs before the end of the 60-day period
7 that begins on the first day of the month
8 which includes—

9 “(I) in the case of a beneficiary
10 with coverage described in clause (ii)
11 of subparagraph (F), the date on
12 which the plan terminates, ceases to
13 provide, or reduces the value of the
14 prescription drug coverage under such
15 plan to below the actuarial value of
16 the coverage provided under the pro-
17 gram under this part; or

18 “(II) in the case of a beneficiary
19 with coverage described in clause (i),
20 (iii), or (iv) of subparagraph (F), the
21 date on which the beneficiary loses eli-
22 gibility for such coverage.

23 “(D) PERIODS TREATED SEPARATELY.—

24 Any increase in an eligible beneficiary’s monthly
25 part D premium under subparagraph (A) with

1 respect to a particular continuous period of eli-
 2 gibility shall not be applicable with respect to
 3 any other continuous period of eligibility which
 4 the beneficiary may have.

5 “(E) CONTINUOUS PERIOD OF ELIGI-
 6 BILITY.—

7 “(i) IN GENERAL.—Subject to clause
 8 (ii), for purposes of this paragraph, an eli-
 9 gible beneficiary’s ‘continuous period of eli-
 10 gibility’ is the period that begins with the
 11 first day on which the beneficiary is eligi-
 12 ble to enroll under section 1836 and ends
 13 with the beneficiary’s death.

14 “(ii) SEPARATE PERIOD.—Any period
 15 during all of which an eligible beneficiary
 16 satisfied paragraph (1) of section 1836
 17 and which terminated in or before the
 18 month preceding the month in which the
 19 beneficiary attained age 65 shall be a sepa-
 20 rate ‘continuous period of eligibility’ with
 21 respect to the beneficiary (and each such
 22 period which terminates shall be deemed
 23 not to have existed for purposes of subse-
 24 quently applying this paragraph).

“(F) CREDITABLE PRESCRIPTION DRUG
 COVERAGE DEFINED.—For purposes of this
 part, the term ‘creditable prescription drug cov-
 erage’ means any of the following:

“(i) MEDICAID PRESCRIPTION DRUG
 COVERAGE.—Prescription drug coverage
 under a medicaid plan under title XIX, in-
 cluding through the Program of All-inclu-
 sive Care for the Elderly (PACE) under
 section 1934 and through a social health
 maintenance organization (referred to in
 section 4104(c) of the Balanced Budget
 Act of 1997), but only if the coverage pro-
 vides coverage of the cost of prescription
 drugs the actuarial value of which (as de-
 fined by the Secretary) to the beneficiary
 equals or exceeds the actuarial value of the
 benefits provided to an individual enrolled
 in the outpatient prescription drug benefit
 program under this part.

“(ii) PRESCRIPTION DRUG COVERAGE
 UNDER A GROUP HEALTH PLAN.—Pre-
 scription drug coverage under a group
 health plan, including a health benefits
 plan under the Federal Employees Health

Benefit Program under chapter 89 of title 5, United States Code, and a qualified retiree prescription drug plan (as defined in section 1860J(e)(3)), but only if the coverage provides coverage of the cost of prescription drugs the actuarial value of which (as defined by the Secretary) to the beneficiary equals or exceeds the actuarial value of the benefits provided to an individual enrolled in the outpatient prescription drug benefit program under this part.

“(iii) STATE PHARMACEUTICAL ASSISTANCE PROGRAM.—Coverage of prescription drugs under a State pharmaceutical assistance program, but only if the coverage provides coverage of the cost of prescription drugs the actuarial value of which (as defined by the Secretary) to the beneficiary equals or exceeds the actuarial value of the benefits provided to an individual enrolled in the outpatient prescription drug benefit program under this part.

“(iv) VETERANS’ COVERAGE OF PRESCRIPTION DRUGS.—Coverage of prescription drugs for veterans, and survivors and

dependents of veterans, under chapter 17 of title 38, United States Code, but only if the coverage provides coverage of the cost of prescription drugs the actuarial value of which (as defined by the Secretary) to the beneficiary equals or exceeds the actuarial value of the benefits provided to an individual enrolled in the outpatient prescription drug benefit program under this part.

“(2) OPEN ENROLLMENT PERIOD FOR CURRENT BENEFICIARIES IN WHICH LATE ENROLLMENT PROCEDURES DO NOT APPLY.—

“(A) IN GENERAL.—The Secretary shall establish an applicable period, which shall begin on the date on which the Secretary first begins to accept elections for enrollment under this part, during which any eligible beneficiary may enroll under this part without the application of the late enrollment procedures established under paragraph (1)(A).

“(B) OPEN ENROLLMENT.—An eligible beneficiary who enrolls under the program under this part pursuant to subparagraph (A) shall be entitled to the benefits under this part beginning on the first day of the month fol-

1 lowing the month in which such enrollment oc-
 2 curs.

3 “(3) SPECIAL ENROLLMENT PERIOD FOR BENE-
 4 FICIARIES WHO INVOLUNTARILY LOSE CREDITABLE
 5 PRESCRIPTION DRUG COVERAGE.—The Secretary
 6 shall establish a special open enrollment period for
 7 an eligible beneficiary that loses creditable prescrip-
 8 tion drug coverage.

9 “(c) PERIOD OF COVERAGE.—

10 “(1) IN GENERAL.—Except as provided in para-
 11 graph (2) and subject to paragraph (3), an eligible
 12 beneficiary’s coverage under the program under this
 13 part shall be effective for the period provided in sec-
 14 tion 1838, as if that section applied to the program
 15 under this part.

16 “(2) OPEN AND SPECIAL ENROLLMENT.—Sub-
 17 ject to paragraph (3), an eligible beneficiary who en-
 18 rolls under the program under this part pursuant to
 19 paragraph (2) or (3) of subsection (b) shall be enti-
 20 tled to the benefits under this part beginning on the
 21 first day of the month following the month in which
 22 such enrollment occurs.

23 “(3) LIMITATION.—Coverage under this part
 24 shall not begin prior to the date the Secretary deter-
 25 mines, in accordance with section 1860A(a)(1), that

1 the Prescription Drug Benefit and Cost Contain-
 2 ment Act of 2003 shall be implemented.

3 “(d) TERMINATION.—

4 “(1) IN GENERAL.—The causes of termination
 5 specified in section 1838 shall apply to this part in
 6 a similar manner as such causes apply to part B.

7 “(2) COVERAGE TERMINATED BY TERMINATION
 8 OF COVERAGE UNDER PARTS A AND B.—

9 “(A) IN GENERAL.—In addition to the
 10 causes of termination specified in paragraph
 11 (1), the Secretary shall terminate an individ-
 12 ual’s coverage under this part if the individual
 13 is no longer enrolled in either part A or B.

14 “(B) EFFECTIVE DATE.—The termination
 15 described in subparagraph (A) shall be effective
 16 on the effective date of termination of coverage
 17 under part A or (if later) under part B.

18 “(3) PROCEDURES REGARDING TERMINATION
 19 OF A BENEFICIARY UNDER A PLAN.—The Secretary
 20 shall establish procedures for determining the status
 21 of an eligible beneficiary’s enrollment under this
 22 part if the beneficiary’s enrollment in a plan offered
 23 by an eligible entity under this part is terminated by
 24 the entity for cause (pursuant to procedures estab-
 25 lished by the Secretary under section 1860C(a)(1)).

1 “ENROLLMENT IN A PLAN

2 “SEC. 1860C. (a) PROCESS.—

3 “(1) ESTABLISHMENT.—

4 “(A) ELECTION.—

5 “(i) IN GENERAL.—The Secretary
6 shall establish a process through which an
7 eligible beneficiary who is enrolled under
8 this part but not enrolled in a
9 Medicare+Choice plan offered by a
10 Medicare+Choice organization—

11 “(I) shall make an annual elec-
12 tion to enroll in any plan offered by
13 an eligible entity that has been award-
14 ed a contract under this part and
15 serves the geographic area in which
16 the beneficiary resides; and

17 “(II) may make an annual elec-
18 tion to change the election under this
19 clause.

20 “(ii) DEFAULT ENROLLMENT.—Such
21 process shall include for the default enroll-
22 ment in such a plan in the case of an eligi-
23 ble beneficiary who is enrolled under this
24 part but who has failed to make an elec-
25 tion of such a plan.

1 “(B) RULES.—In establishing the process
2 under subparagraph (A), the Secretary shall—

3 “(i) use rules similar to the rules for
4 enrollment, disenrollment, and termination
5 of enrollment with a Medicare+Choice
6 plan under section 1851, including—

7 “(I) the establishment of special
8 election periods under subsection
9 (e)(4) of such section; and

10 “(II) the application of the guar-
11 anteed issue and renewal provisions of
12 subsection (g) of such section (other
13 than paragraph (3)(C)(i), relating to
14 default enrollment); and

15 “(ii) coordinate enrollments,
16 disenrollments, and terminations of enroll-
17 ment under part C with enrollments,
18 disenrollments, and terminations of enroll-
19 ment under this part.

20 “(2) FIRST ENROLLMENT PERIOD FOR PLAN
21 ENROLLMENT.—The process developed under para-
22 graph (1) shall—

23 “(A) ensure—

24 “(i) that an individual who meets or
25 will meet the definition of an eligible bene-

1 ficiary under section 1860(2) upon the
 2 date of implementation of the Prescription
 3 Drug Benefit and Cost Containment Act of
 4 2003, as determined by the Secretary in
 5 accordance with section 1860A(a)(1), is
 6 permitted to enroll with an eligible entity
 7 prior to such date; and

8 “(ii) that coverage under this part for
 9 such an individual is effective as of such
 10 date; and

11 “(B) be coordinated with the open enroll-
 12 ment period under section 1860B(b)(2).

13 “(b) MEDICARE+CHOICE ENROLLEES.—

14 “(1) IN GENERAL.—An eligible beneficiary who
 15 is enrolled under this part and enrolled in a
 16 Medicare+Choice plan offered by a
 17 Medicare+Choice organization shall receive coverage
 18 of covered outpatient drugs under this part through
 19 such plan.

20 “(2) RULES.—Enrollment in a
 21 Medicare+Choice plan is subject to the rules for en-
 22 rollment in such a plan under section 1851.

23 “PROVIDING INFORMATION TO BENEFICIARIES

24 “SEC. 1860D. (a) ACTIVITIES.—

25 “(1) IN GENERAL.—The Secretary shall con-
 26 duct activities that are designed to broadly dissemi-

1 nate information to eligible beneficiaries (and pro-
 2 spective eligible beneficiaries) regarding the coverage
 3 provided under this part.

4 “(2) SPECIAL RULE FOR FIRST ENROLLMENT
 5 UNDER THE PROGRAM.—To the extent practicable,
 6 the activities described in paragraph (1) shall ensure
 7 that individuals who meet or will meet the definition
 8 of an eligible beneficiary under section 1860(2) upon
 9 the date of implementation of the Prescription Drug
 10 Benefit and Cost Containment Act of 2003, as de-
 11 termined by the Secretary in accordance with section
 12 1860A(a)(1), and other prospective eligible bene-
 13 ficiaries, are provided with such information at least
 14 30 days prior to the open enrollment period de-
 15 scribed in section 1860B(b)(2).

16 “(b) REQUIREMENTS.—

17 “(1) IN GENERAL.—The activities described in
 18 subsection (a) shall—

19 “(A) be similar to the activities performed
 20 by the Secretary under section 1851(d);

21 “(B) be coordinated with the activities per-
 22 formed by the Secretary under such section and
 23 under section 1804; and

24 “(C) provide for the dissemination of infor-
 25 mation comparing the plans offered by eligible

1 entities under this part that are available to eli-
2 gible beneficiaries residing in an area.

3 “(2) COMPARATIVE INFORMATION.—The com-
4 parative information described in paragraph (1)(C)
5 shall include a comparison of the following:

6 “(A) BENEFITS.—The benefits provided
7 under the plan, including the prices bene-
8 ficiaries will be charged for covered outpatient
9 drugs, any preferred pharmacy networks used
10 by the eligible entity under the plan, and the
11 formularies and appeals processes under the
12 plan.

13 “(B) QUALITY AND PERFORMANCE.—To
14 the extent available, the quality and perform-
15 ance of the eligible entity offering the plan.

16 “(C) BENEFICIARY COST-SHARING.—The
17 cost-sharing required of eligible beneficiaries
18 under the plan.

19 “(D) CONSUMER SATISFACTION SUR-
20 VEYS.—To the extent available, the results of
21 consumer satisfaction surveys regarding the
22 plan and the eligible entity offering such plan.

23 “(E) ADDITIONAL INFORMATION.—Such
24 additional information as the Secretary may
25 prescribe.

1 “(3) INFORMATION STANDARDS.—The Sec-
 2 retary shall develop standards to ensure that the in-
 3 formation provided to eligible beneficiaries under
 4 this part is complete, accurate, and uniform.

5 “(c) USE OF MEDICARE CONSUMER COALITIONS TO
 6 PROVIDE INFORMATION.—

7 “(1) IN GENERAL.—The Secretary may con-
 8 tract with Medicare Consumer Coalitions to conduct
 9 the informational activities under—

10 “(A) this section;

11 “(B) section 1851(d); and

12 “(C) section 1804.

13 “(2) SELECTION OF COALITIONS.—If the Sec-
 14 retary determines the use of Medicare Consumer
 15 Coalitions to be appropriate, the Secretary shall—

16 “(A) develop and disseminate, in such
 17 areas as the Secretary determines appropriate,
 18 a request for proposals for Medicare Consumer
 19 Coalitions to contract with the Secretary in
 20 order to conduct any of the informational ac-
 21 tivities described in paragraph (1); and

22 “(B) select a proposal of a Medicare Con-
 23 sumer Coalition to conduct the informational
 24 activities in each such area, with a preference
 25 for broad participation by organizations with

8 “(4) AUTHORIZATION OF APPROPRIATIONS.—
9 There are authorized to be appropriated, out of any
10 moneys in the Treasury not otherwise appropriated,
11 to the Secretary such sums as may be necessary to
12 contract with Medicare Consumer Coalitions under
13 this section.

20 “PREMIUMS

23 “(1) ESTABLISHMENT OF RATE.—The Sec-
24 retary shall determine and promulgate, during Sep-
25 tember of each year (beginning with the first Sep-
26 tember after the date that is 1 year after the imple-

1 mentation date of the Prescription Drug Benefit and
 2 Cost Containment Act of 2003, as determined by the
 3 Secretary in accordance with section 1860A(a)(1)) a
 4 monthly part D premium rate for the succeeding
 5 year.

6 “(2) AMOUNT.—The Secretary shall determine
 7 the monthly part D premium rate as follows:

8 “(A) PREMIUM FOR INITIAL PERIOD OF
 9 IMPLEMENTATION.—The monthly part D pre-
 10 mium rate for any months occurring during the
 11 period that begins on the implementation date
 12 of the Prescription Drug Benefit and Cost Con-
 13 tainment Act of 2003, as determined by the
 14 Secretary in accordance with section
 15 1860A(a)(1) and ends on the first December 31
 16 that occurs after the September described in
 17 paragraph (1), shall be \$25.

18 “(B) INFLATION ADJUSTMENT OF PRE-
 19 MIUM FOR SUBSEQUENT YEARS.—

20 “(i) IN GENERAL.—Subject to clause
 21 (ii), in the case of any calendar year begin-
 22 ning after the period described in subpara-
 23 graph (A), the monthly part D premium
 24 rate for the year shall be the amount de-

1 scribed in subparagraph (A) increased by
2 an amount equal to—

3 “(I) such dollar amount, multi-
4 plied by

5 “(II) the percentage (if any) by
6 which the amount of the average an-
7 nual per capita aggregate expendi-
8 tures payable from the Prescription
9 Drug Account for the year (as esti-
10 mated under section 1860J(c)(2)(C))
11 exceeds the amount of such expendi-
12 tures in the period described in sub-
13 paragraph (A).

14 “(ii) ROUNDING.—If the monthly part
15 D premium rate determined under clause
16 (i) is not a multiple of \$1, such rate shall
17 be rounded to the nearest multiple of \$1.

18 “(b) COLLECTION OF PART D PREMIUM.—The
19 monthly part D premium applicable to an eligible bene-
20 ficiary under this part (after application of any increase
21 under section 1860B(b)(1)) shall be collected and credited
22 to the Prescription Drug Account in the same manner as
23 the monthly premium determined under section 1839 is
24 collected and credited to the Federal Supplementary Med-
25 ical Insurance Trust Fund under section 1840.

1 “OUTPATIENT PRESCRIPTION DRUG BENEFITS

2 “SEC. 1860F. (a) REQUIREMENT.—A plan offered by
3 an eligible entity under this part shall provide eligible
4 beneficiaries enrolled in such plan with—

5 “(1) coverage of covered outpatient drugs—

6 “(A) without the application of any deduct-
7 ible; and

8 “(B) with the cost-sharing described in
9 subsection (b); and

10 “(2) access to negotiated prices for such drugs
11 under subsection (c).

12 “(b) COST-SHARING.—

13 “(1) ESTABLISHMENT.—

14 “(A) IN GENERAL.—Subject to the suc-
15 ceeding provisions of this subsection, an eligible
16 beneficiary shall be responsible for making a
17 payment for a covered outpatient drug fur-
18 nished to the beneficiary in a year in an
19 amount equal to the applicable percentage of
20 the cost of the drug.

21 “(B) APPLICABLE PERCENTAGE DE-
22 FINED.—For purposes of subparagraph (A), the
23 term ‘applicable percentage’ means, with re-
24 spect to any covered outpatient drug provided
25 to an eligible beneficiary in a year—

“(i) 50 percent to the extent the out-of-pocket costs of the beneficiary for such drug, when added to the out-of-pocket costs of the beneficiary for covered outpatient drugs previously provided in the year, do not exceed \$3,700; and

“(ii) 0 percent to the extent such expenses, when so added, would exceed \$3,700.

“(C) APPLICATION OF OUT-OF-POCKET COSTS.—For purposes of subparagraph (B)—

“(i) out-of-pocket costs shall only include costs incurred for the cost-sharing described in this subsection; but

“(ii) such costs shall be treated as incurred without regard to whether the individual or another person, including a State program or other third-party coverage, has paid for such costs.

“(2) REDUCTION OR SUBSTITUTION BY ELIGIBLE ENTITY.—An eligible entity may reduce the applicable cost-sharing amount that an eligible beneficiary is subject to under paragraph (1) or substitute a copayment amount if the Secretary determines that such reduction or substitution—

1 “(A) is tied to the performance require-
 2 ments described in section 1860I(b)(1)(C); and

3 “(B) will not result in an increase in the
 4 expenditures made from the Prescription Drug
 5 Account.

6 “(3) TREATMENT OF MEDICALLY NECESSARY
 7 NONFORMULARY DRUGS.—The eligible entity shall
 8 treat a covered outpatient drug that is not included
 9 on the formulary established by the eligible entity
 10 (pursuant to section 1860H(c)) for the plan as a
 11 drug so included if the nonformulary drug is deter-
 12 mined (pursuant to subparagraph (D) or (E) of sec-
 13 tion 1860H(a)(4)) to be medically necessary.

14 “(4) BENEFICIARY RESPONSIBLE FOR NEGO-
 15 TIATED PRICE OF NONFORMULARY DRUGS.—In the
 16 case of a covered outpatient drug that is dispensed
 17 to an eligible beneficiary and that is not included on
 18 the formulary established by the eligible entity (pur-
 19 suant to section 1860H(c)) for the plan (and not
 20 treated as a drug on the formulary under paragraph
 21 (3)), the beneficiary shall be responsible for the ne-
 22 gotiated price for the drug (as reported to the Sec-
 23 retary pursuant to section 1860H(a)(6)(A)).

24 “(5) COST-SHARING MAY NOT EXCEED NEGO-
 25 TIATED PRICE.—If the amount of cost-sharing for a

covered outpatient drug that would otherwise be required under this subsection (but for this paragraph) is greater than the negotiated price for the drug (as reported to the Secretary pursuant to section 1860H(a)(6)(A)), then the amount of such cost-sharing shall be reduced to an amount equal to such negotiated price.

“(6) INFLATION ADJUSTMENT FOR ANNUAL OUT-OF-POCKET LIMIT FOR SUBSEQUENT YEARS.—

“(A) IN GENERAL.—For any year after the period described in section 1860E(a)(2)(A), the dollar amounts specified in clauses (i) and (ii) of paragraph (1)(B) are equal to the dollar amounts determined under such clauses (or this paragraph) for the previous year increased by the annual percentage increase specified in subparagraph (B).

“(B) ANNUAL PERCENTAGE INCREASE SPECIFIED IN SUBPARAGRAPH (B).—The annual percentage increase specified in this subparagraph for a year is equal to the annual percentage increase in average per capita aggregate expenditures for covered outpatient drugs in the United States for medicare beneficiaries, as de-

1 terminated by the Secretary for the 12-month pe-
2 riod ending in July of the previous year.

3 “(C) ROUNDING.—If any amount deter-
4 mined under subparagraph (A) is not a multiple
5 of \$1, such amount shall be rounded to the
6 nearest multiple of \$1.

7 “(c) ACCESS TO NEGOTIATED PRICES.—

8 “(1) ACCESS.—Under a plan offered by an eli-
9 gible entity with a contract under this part, the eligi-
10 ble entity offering such plan shall provide eligible
11 beneficiaries enrolled in such plan with access to ne-
12 gotiated prices (including applicable discounts) used
13 for payment for covered outpatient drugs, regardless
14 of the fact that only partial benefits may be payable
15 under the coverage with respect to such drugs be-
16 cause of the application of the cost-sharing under
17 subsection (b).

18 “(2) MEDICAID RELATED PROVISIONS.—Insofar
19 as a State elects to provide medical assistance under
20 title XIX for a drug based on the prices negotiated
21 under a plan under this part, the requirements of
22 section 1927 shall not apply to such drugs. The
23 prices negotiated under a plan under this part with
24 respect to covered outpatient drugs, under a
25 Medicare+Choice plan with respect to such drugs,

1 or under a qualified retiree prescription drug plan
 2 (as defined in section 1860J(e)(3)) with respect to
 3 such drugs, on behalf of eligible beneficiaries, shall
 4 (notwithstanding any other provision of law) not be
 5 taken into account for the purposes of establishing
 6 the best price under section 1927(c)(1)(C).

7 “ENTITIES ELIGIBLE TO PROVIDE OUTPATIENT DRUG
 8 BENEFIT

9 “SEC. 1860G. (a) ESTABLISHMENT OF PANELS OF
 10 PLANS AVAILABLE IN AN AREA.—

11 “(1) IN GENERAL.—The Secretary shall estab-
 12 lish procedures under which the Secretary—

13 “(A) accepts bids submitted by eligible en-
 14 tities for the plans which such entities intend to
 15 offer in an area established under subsection
 16 (b); and

17 “(B) awards contracts to such entities to
 18 provide such plans to eligible beneficiaries in
 19 the area.

20 “(2) COMPETITIVE PROCEDURES.—Competitive
 21 procedures (as defined in section 4(5) of the Office
 22 of Federal Procurement Policy Act (41 U.S.C.
 23 403(5))) shall be used to enter into contracts under
 24 this part.

25 “(b) AREA FOR CONTRACTS.—

26 “(1) REGIONAL BASIS.—

1 “(A) IN GENERAL.—Except as provided in
 2 subparagraph (B) and subject to paragraph (2),
 3 the contract entered into between the Secretary
 4 and an eligible entity with respect to a plan
 5 shall require the eligible entity to provide cov-
 6 erage of covered outpatient drugs under the
 7 plan in a region established by the Secretary
 8 under paragraph (2).

9 “(B) PARTIAL REGIONAL BASIS.—

10 “(i) IN GENERAL.—If determined ap-
 11 propriate by the Secretary, the Secretary
 12 may permit the coverage described in sub-
 13 paragraph (A) to be provided in a partial
 14 region determined appropriate by the Sec-
 15 retary.

16 “(ii) REQUIREMENTS.—If the Sec-
 17 retary permits coverage pursuant to clause
 18 (i), the Secretary shall ensure that the par-
 19 tial region in which coverage is provided
 20 is—

21 “(I) at least the size of the com-
 22 mercial service area of the eligible en-
 23 tity for that area; and

24 “(II) not smaller than a State.

25 “(2) ESTABLISHMENT OF REGIONS.—

“(A) IN GENERAL.—In establishing regions for contracts under this part, the Secretary shall—

“(i) take into account the number of eligible beneficiaries in an area in order to encourage participation by eligible entities; and

“(ii) ensure that there are at least 10 different regions in the United States.

“(B) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—The establishment of regions and partial regions under this section shall not be subject to administrative or judicial review.

“(c) SUBMISSION OF BIDS.—

“(1) SUBMISSION.—

“(A) IN GENERAL.—Subject to subparagraph (B), each eligible entity desiring to offer a plan under this part in an area shall submit a bid with respect to such plan to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may reasonably require.

“(B) BID THAT COVERS MULTIPLE AREAS.—The Secretary shall permit an eligible

1 entity to submit a single bid for multiple areas
2 if the bid is applicable to all such areas.

3 “(2) REQUIRED INFORMATION.—A bid de-
4 scribed in paragraph (1) shall include—

5 “(A) a proposal for the estimated prices of
6 covered outpatient drugs and the projected an-
7 nual increases in such prices, including differen-
8 tials between formulary and nonformulary
9 prices, if applicable;

10 “(B) a statement regarding the amount
11 that the entity will charge the Secretary for
12 managing, administering, and delivering the
13 benefits under the contract;

14 “(C) a statement regarding whether the
15 entity will reduce the applicable cost-sharing
16 amount or substitute a copayment amount pur-
17 suant to section 1860F(b)(2) and if so, the
18 amount of such reduction or copayments and
19 how such reduction or substitution is tied to the
20 performance requirements described in section
21 1860I(b)(1)(C);

22 “(D) a detailed description of the perform-
23 ance requirements for which the payments to
24 the entity will be subject to risk pursuant to
25 section 1860I(b)(1)(C);

1 “(E) a detailed description of access to
2 pharmacy services provided under the plan, in-
3 cluding proposed contracts with local pharmacy
4 providers designed to ensure access and pro-
5 posed compensation for local pharmacists’ serv-
6 ices;

7 “(F) with respect to the formulary used by
8 the entity, a detailed description of the proce-
9 dures and standards the entity will use for—

10 “(i) adding new drugs to a thera-
11 peutic class within the formulary; and

12 “(ii) determining when and how often
13 the formulary should be modified;

14 “(G) a detailed description of any owner-
15 ship or shared financial interests with other en-
16 tities involved in the delivery of the benefit as
17 proposed under the plan;

18 “(H) a detailed description of the entity’s
19 estimated marketing and advertising expendi-
20 tures related to enrolling eligible beneficiaries
21 under the plan and retaining such enrollment;
22 and

23 “(I) such other information that the Sec-
24 retary determines is necessary in order to carry

1 out this part, including information relating to
2 the bidding process under this part.

3 “(d) ACCESS TO BENEFITS IN CERTAIN AREAS.—

4 “(1) AREAS NOT COVERED BY CONTRACTS.—

5 The Secretary shall develop procedures for the provi-
6 sion of covered outpatient drugs under this part to
7 each eligible beneficiary enrolled under this part that
8 resides in an area that is not covered by any con-
9 tract under this part.

10 “(2) BENEFICIARIES RESIDING IN DIFFERENT
11 LOCATIONS.—The Secretary shall develop procedures
12 to ensure that each eligible beneficiary enrolled
13 under this part that resides in different areas in a
14 year is provided the benefits under this part
15 throughout the entire year.

16 “(3) SPECIAL ATTENTION TO RURAL AND
17 HARD-TO-SERVE AREAS.—

18 “(A) IN GENERAL.—The Secretary shall
19 ensure that all eligible beneficiaries have access
20 to the full range of benefits under this part,
21 and shall give special attention to access, phar-
22 macist counseling, and delivery in rural and
23 hard-to-serve areas (as the Secretary may de-
24 fine by regulation).

1 “(B) SPECIAL ATTENTION DEFINED.—For
2 purposes of subparagraph (A), the term ‘special
3 attention’ may include bonus payments to retail
4 pharmacists in rural areas, extra payments to
5 eligible entities for the cost of rapid delivery of
6 pharmaceuticals, and any other actions the Sec-
7 retary determines are necessary to ensure full
8 access to benefits under this part by eligible
9 beneficiaries residing in rural and hard-to-serve
10 areas.

11 “(C) GAO REPORT.—Not later than 2
12 years after the date of enactment of the Pre-
13 scription Drug Benefit and Cost Containment
14 Act of 2003, the Comptroller General of the
15 United States shall submit to Congress a report
16 on the access to benefits under this part by eli-
17 gible beneficiaries residing in rural and hard-to-
18 serve areas, together with any recommendations
19 of the Comptroller General regarding any addi-
20 tional steps the Secretary may need to take to
21 ensure the access of eligible beneficiaries to
22 such benefits.

23 “(e) AWARDING OF CONTRACTS.—

24 “(1) NUMBER OF CONTRACTS.—The Secretary
25 shall, consistent with the requirements of this part

1 and the goal of containing costs under this title,
2 award in a competitive manner at least 2 contracts
3 to offer a plan in an area, unless only 1 bidding
4 entity (and the plan offered by the entity) meets the
5 minimum standards specified under this part and by
6 the Secretary.

7 “(2) DETERMINATION.—In determining which
8 of the eligible entities that submitted bids that meet
9 the minimum standards specified under this part
10 and by the Secretary to award a contract, the Sec-
11 retary shall consider the comparative merits of each
12 bid, as determined on the basis of the past perform-
13 ance of the entity and other relevant factors, with
14 respect to—

15 “(A) how well the entity (and the plan of-
16 fered by the entity) meet such minimum stand-
17 ards;

18 “(B) the amount that the entity will
19 charge the Secretary for managing, admin-
20 istering, and delivering the benefits under the
21 contract;

22 “(C) the performance requirements for
23 which the payments to the entity will be subject
24 to risk pursuant to section 1860I(b)(1)(C);

1 “(D) the proposed negotiated prices of cov-
 2 ered outpatient drugs and annual increases in
 3 such prices;

4 “(E) the factors described in section
 5 1860D(b)(2);

6 “(F) prior experience of the entity in man-
 7 aging, administering, and delivering a prescrip-
 8 tion drug benefit program;

9 “(G) effectiveness of the entity and plan in
 10 containing costs through pricing incentives and
 11 utilization management; and

12 “(H) such other factors as the Secretary
 13 deems necessary to evaluate the merits of each
 14 bid.

15 “(3) EXCEPTION TO CONFLICT OF INTEREST
 16 RULES.—In awarding contracts under this part, the
 17 Secretary may waive conflict of interest laws gen-
 18 erally applicable to Federal acquisitions (subject to
 19 such safeguards as the Secretary may find necessary
 20 to impose) in circumstances where the Secretary
 21 finds that such waiver—

22 “(A) is not inconsistent with the—

23 “(i) purposes of the programs under
 24 this title; or

1 “(ii) best interests of beneficiaries en-
 2 rolled under this part; and

3 “(B) permits a sufficient level of competi-
 4 tion for such contracts, promotes efficiency of
 5 benefits administration, or otherwise serves the
 6 objectives of the program under this part.

7 “(4) NO ADMINISTRATIVE OR JUDICIAL RE-
 8 VIEW.—The determination of the Secretary to award
 9 or not award a contract to an eligible entity with re-
 10 spect to a plan under this part shall not be subject
 11 to administrative or judicial review.

12 “(f) APPROVAL OF MARKETING MATERIAL AND AP-
 13 PPLICATION FORMS.—The provisions of section 1851(h)
 14 shall apply to marketing material and application forms
 15 under this part in the same manner as such provisions
 16 apply to marketing material and application forms under
 17 part C.

18 “(g) DURATION OF CONTRACTS.—Each contract
 19 awarded under this part shall be for a term of at least
 20 2 years but not more than 5 years, as determined by the
 21 Secretary.

22 “MINIMUM STANDARDS FOR ELIGIBLE ENTITIES

23 “SEC. 1860H. (a) IN GENERAL.—The Secretary
 24 shall not award a contract to an eligible entity under this
 25 part unless the Secretary finds that the eligible entity

1 agrees to comply with such terms and conditions as the
 2 Secretary shall specify, including the following:

3 “(1) QUALITY AND FINANCIAL STANDARDS.—

4 The eligible entity meets the quality and financial
 5 standards specified by the Secretary.

6 “(2) PROCEDURES TO ENSURE PROPER UTILI-
 7 ZATION, COMPLIANCE, AND AVOIDANCE OF ADVERSE
 8 DRUG REACTIONS.—

9 “(A) IN GENERAL.—The eligible entity has
 10 in place drug utilization review procedures to
 11 ensure—

12 “(i) the appropriate utilization by eli-
 13 gible beneficiaries enrolled in the plan cov-
 14 ered by the contract of the benefits to be
 15 provided under the plan;

16 “(ii) the avoidance of adverse drug re-
 17 actions among such beneficiaries, including
 18 problems due to therapeutic duplication,
 19 drug-disease contraindications, drug-drug
 20 interactions (including serious interactions
 21 with nonprescription or over-the-counter
 22 drugs), incorrect drug dosage or duration
 23 of drug treatment, drug-allergy inter-
 24 actions, and clinical abuse and misuse; and

1 “(iii) the reasonable application of
 2 peer-reviewed medical literature pertaining
 3 to improvements in pharmaceutical safety
 4 and appropriate use of drugs.

5 “(B) AUTHORITY TO USE CERTAIN COM-
 6 PENDIA AND LITERATURE.—The eligible entity
 7 may use the compendia and literature referred
 8 to in clauses (i) and (ii), respectively, of section
 9 1927(g)(1)(B) as a source for the utilization re-
 10 view under subparagraph (A).

11 “(3) ELECTRONIC PRESCRIPTION PROGRAM.—

12 “(A) IN GENERAL.—The eligible entity has
 13 in place, as soon as practicable, an electronic
 14 prescription drug program that includes at least
 15 the following components, consistent with na-
 16 tional standards established under subpara-
 17 graph (B):

18 “(i) ELECTRONIC TRANSMITTAL OF
 19 PRESCRIPTIONS.—Prescriptions are only
 20 received electronically, except in emergency
 21 cases and other exceptional circumstances
 22 recognized by the Secretary.

23 “(ii) PROVISION OF INFORMATION TO
 24 PRESCRIBING HEALTH CARE PROFES-
 25 SIONAL.—The program provides, upon

transmittal of a prescription by a prescribing health care professional, for transmittal by the pharmacist to the professional of information that includes—

“(I) information (to the extent available and feasible) on the drugs being prescribed for that patient and other information relating to the medical history or condition of the patient that may be relevant to the appropriate prescription for that patient;

“(II) cost-effective alternatives (if any) for the use of the drug prescribed; and

“(III) information on the drugs included in the applicable formulary.

To the extent feasible, such program shall permit the prescribing health care professional to provide (and be provided) related information on an interactive, real-time basis.

“(B) STANDARDS.—

“(i) DEVELOPMENT.—The Secretary shall provide for the development of national standards relating to the electronic

1 prescription drug program described in
2 subparagraph (A). Such standards shall be
3 compatible with standards established
4 under part C of title XI.

5 “(ii) ADVISORY TASK FORCE.—In de-
6 veloping such standards, the Secretary
7 shall establish a task force that includes
8 representatives of physicians, hospitals,
9 pharmacists, and technology experts and
10 representatives of the Departments of Vet-
11 erans Affairs and Defense and other ap-
12 propriate Federal agencies to provide rec-
13 ommendations to the Secretary on such
14 standards, including recommendations re-
15 lating to the following:

16 “(I) The range of available com-
17 puterized prescribing software and
18 hardware and their costs to develop
19 and implement.

20 “(II) The extent to which such
21 systems reduce medication errors and
22 can be readily implemented by physi-
23 cians and hospitals.

1 “(III) Efforts to develop a com-
2 mon software platform for computer-
3 ized prescribing.

4 “(IV) The cost of implementing
5 such systems in the range of hospital
6 and physician office settings, includ-
7 ing hardware, software, and training
8 costs.

9 “(V) Implementation issues as
10 they relate to part C of title XI, and
11 current Federal and State prescribing
12 laws and regulations and their impact
13 on implementation of computerized
14 prescribing.

15 “(iii) DEADLINES.—

16 “(I) The Secretary shall establish
17 the task force under clause (ii) as
18 soon as possible after the date of en-
19 actment of the Prescription Drug
20 Benefit and Cost Containment Act of
21 2003.

22 “(II) The task force shall submit
23 recommendations to the Secretary by
24 not later than 9 months after the date

1 the task force is first established
2 under clause (i).

3 “(III) The Secretary shall de-
4 velop and promulgate the national
5 standards referred to in clause (ii) by
6 not later than 1 year after the date
7 the task force submits recommenda-
8 tions to the Secretary.

9 “(C) DELAY IN IMPLEMENTATION NOT TO
10 DELAY IMPLEMENTATION OF DRUG BENEFIT.—
11 Any delay in the development and implementa-
12 tion of the national standards referred to in
13 subparagraph (B)(ii) or in the implementation
14 of an electronic prescription drug program in
15 accordance with such standards by an eligible
16 entity shall not delay the implementation of the
17 outpatient prescription drug benefit program
18 established under this part. In accordance with
19 section 1860A(a)(1), the Secretary shall imple-
20 ment the outpatient prescription drug benefit
21 program as soon as possible after the date of
22 enactment of the Prescription Drug Benefit and
23 Cost Containment Act of 2003 and shall waive
24 compliance with any requirements related to the
25 electronic prescription drug program required

1 under this paragraph to the extent necessary
2 until such time as the requirements for the pro-
3 gram are established.

4 “(D) WAIVER OF APPLICATION FOR CER-
5 TAIN RURAL PROVIDERS.—If the Secretary de-
6 termines that it is unduly burdensome on pro-
7 viders in rural areas to comply with the require-
8 ments under this paragraph, the Secretary may
9 waive such requirements for such providers.

10 “(E) GRANT PROGRAM TO PROVIDE AS-
11 SISTANCE IN IMPLEMENTING ELECTRONIC PRE-
12 SCRIPTIION DRUG PROGRAMS.—

13 “(i) IN GENERAL.—The Secretary is
14 authorized to establish a grant program to
15 provide assistance to health care providers
16 in implementing electronic prescription
17 drug programs pursuant to this paragraph.

18 “(ii) AUTHORIZATION OF APPROPRIA-
19 TIONS.—For the purpose of carrying out
20 clause (i), there are authorized to be ap-
21 propriated such sums as may be necessary.

22 “(4) PATIENT PROTECTIONS.—

23 “(A) ACCESS.—

24 “(i) IN GENERAL.—The eligible entity
25 ensures that the covered outpatient drugs

1 are accessible and convenient to eligible
2 beneficiaries enrolled in the plan covered
3 by the contract, including by offering the
4 services 24 hours a day and 7 days a week
5 for emergencies.

6 “(ii) AGREEMENTS WITH PHAR-
7 MACIES.—

8 “(I) IN GENERAL.—The eligible
9 entity shall enter into a participation
10 agreement with any pharmacy that
11 meets the requirements of subsection
12 (d) to dispense covered prescription
13 drugs to eligible beneficiaries under
14 this part.

15 “(II) REQUIREMENT REGARDING
16 PARTICIPATION.—The eligible entity
17 shall include terms in such agree-
18 ments that secure the participation of
19 sufficient numbers of pharmacies to
20 ensure convenient access (including
21 adequate emergency access).

22 “(III) DISPENSING FEE.—Such
23 agreements shall include the payment
24 of a reasonable dispensing fee for cov-

1 ered outpatient drugs dispensed to a
2 beneficiary under the agreement.

3 “(iii) PREFERRED PHARMACY NET-
4 WORKS.—If the eligible entity utilizes a
5 preferred pharmacy network, the network
6 complies with the standards under sub-
7 section (e).

8 “(B) ENSURING THAT BENEFICIARIES ARE
9 NOT OVERCHARGED.—The eligible entity has
10 procedures in place to ensure that each phar-
11 macy with a participation agreement under this
12 part with the entity complies with the require-
13 ments under subsection (d)(1)(C) (relating to
14 adherence to negotiated prices).

15 “(C) CONTINUITY OF CARE.—

16 “(i) IN GENERAL.—The eligible entity
17 ensures that, in the case of an eligible ben-
18 eficiary who loses coverage under this part
19 with such entity under circumstances that
20 would permit a special election period (as
21 established by the Secretary under section
22 1860C(a)(1)), the entity will continue to
23 provide coverage under this part to such
24 beneficiary until the beneficiary enrolls and
25 receives such coverage with another eligible

entity under this part or, if eligible, with a Medicare+Choice organization.

“(ii) LIMITED PERIOD.—In no event shall an eligible entity be required to provide the extended coverage required under clause (i) beyond the date which is 30 days after the coverage with such entity would have terminated but for this subparagraph.

“(D) PROCEDURES REGARDING THE DETERMINATION OF DRUGS THAT ARE MEDICALLY NECESSARY.—

“(i) IN GENERAL.—The eligible entity has in place procedures on a case-by-case basis to treat a drug not included on the formulary of the plan as a drug on the formulary under this part if the formulary drug for the treatment of the same condition is determined—

“(I) to be not as effective for the enrollee in preventing or slowing the deterioration of, or improving or maintaining, the health of the enrollee; or

“(II) to have a significant adverse effect on the enrollee.

1 “(ii) REQUIREMENT.—The procedures
 2 under clause (i) shall require that deter-
 3 minations under such clause are based on
 4 professional medical judgment, the medical
 5 condition of the enrollee, and other medical
 6 evidence.

7 “(E) PROCEDURES REGARDING APPEAL
 8 RIGHTS WITH RESPECT TO DENIALS OF
 9 CARE.—The eligible entity has in place proce-
 10 dures to ensure—

11 “(i) a timely internal review for reso-
 12 lution of denials of coverage (in whole or
 13 in part and including those regarding the
 14 coverage of drugs not included on the for-
 15 mulary of the plan as drugs so included) in
 16 accordance with the medical exigencies of
 17 the case and a timely resolution of com-
 18 plaints, by enrollees in the plan, or by pro-
 19 viders, pharmacists, and other individuals
 20 acting on behalf of each such enrollee (with
 21 the enrollee’s consent) in accordance with
 22 requirements (as established by the Sec-
 23 retary) that are comparable to such re-
 24 quirements for Medicare+Choice organiza-
 25 tions under part C (and are not less favor-

1 able to the enrollee than such requirements
2 under such part as in effect on the date of
3 enactment of the Prescription Drug Ben-
4 efit and Cost Containment Act of 2003);

5 “(ii) that the entity complies in a
6 timely manner with requirements estab-
7 lished by the Secretary that (I) provide for
8 an external review by an independent enti-
9 ty selected by the Secretary of denials of
10 coverage described in clause (i) not re-
11 solved in the favor of the beneficiary (or
12 other complainant) under the process de-
13 scribed in such clause, and (II) are com-
14 parable to the external review requirements
15 established for Medicare+Choice organiza-
16 tions under part C (and are not less favor-
17 able to the enrollee than such requirements
18 under such part as in effect on the date of
19 enactment of the Prescription Drug Ben-
20 efit and Cost Containment Act of 2003);
21 and

22 “(iii) that enrollees are provided with
23 information regarding the appeals proce-
24 dures under this part at the time of enroll-

1 ment with the entity and upon request
2 thereafter.

3 “(F) PROCEDURES REGARDING PATIENT
4 CONFIDENTIALITY.—Insofar as an eligible enti-
5 ty maintains individually identifiable medical
6 records or other health information regarding
7 eligible beneficiaries enrolled in the plan that is
8 covered by the contract, the entity has in place
9 procedures to—

10 “(i) safeguard the privacy of any indi-
11 vidually identifiable beneficiary informa-
12 tion;

13 “(ii) maintain such records and infor-
14 mation in a manner that is accurate and
15 timely;

16 “(iii) ensure timely access by such
17 beneficiaries to such records and informa-
18 tion; and

19 “(iv) otherwise comply with applicable
20 laws relating to patient confidentiality.

21 “(G) PROCEDURES REGARDING TRANSFER
22 OF MEDICAL RECORDS.—

23 “(i) IN GENERAL.—The eligible entity
24 has in place procedures for the timely
25 transfer of records and information de-

scribed in subparagraph (F) (with respect to a beneficiary who loses coverage under this part with the entity and enrolls with another entity (including a Medicare+Choice organization) under this part) to such other entity.

“(ii) PATIENT CONFIDENTIALITY.—

The procedures described in clause (i) shall comply with the patient confidentiality procedures described in subparagraph (F).

“(H) PROCEDURES REGARDING MEDICAL ERRORS.—The eligible entity has in place procedures for—

“(i) working with the Secretary to deter medical errors related to the provision of covered outpatient drugs; and

“(ii) ensuring that pharmacies with a contract with the entity have in place procedures to deter medical errors related to the provision of covered outpatient drugs.

“(5) PROCEDURES TO CONTROL FRAUD, ABUSE, AND WASTE.—

“(A) IN GENERAL.—The eligible entity has in place procedures to control fraud, abuse, and waste.

1 “(B) APPLICABILITY OF FRAUD AND
2 ABUSE PROVISIONS.—The provisions of section
3 1128 through 1128C (relating to fraud and
4 abuse) apply to eligible entities with contracts
5 under this part.

6 “(6) REPORTING REQUIREMENTS.—

7 “(A) IN GENERAL.—The eligible entity
8 provides the Secretary with reports containing
9 information regarding the following:

10 “(i) The negotiated prices that the eli-
11 gible entity is paying for covered out-
12 patient drugs.

13 “(ii) The prices that eligible bene-
14 ficiaries enrolled in the plan that is covered
15 by the contract will be charged for covered
16 outpatient drugs.

17 “(iii) The management costs of pro-
18 viding such benefits.

19 “(iv) Utilization of such benefits.

20 “(v) Marketing and advertising ex-
21 penditures related to enrolling and retain-
22 ing eligible beneficiaries.

23 “(B) TIMEFRAME FOR SUBMITTING RE-
24 PORTS.—

1 “(i) IN GENERAL.—The eligible entity
2 shall submit a report described in subpara-
3 graph (A) to the Secretary within 3
4 months after the end of each 12-month pe-
5 riod in which the eligible entity has a con-
6 tract under this part. Such report shall
7 contain information concerning the benefits
8 provided during such 12-month period.

9 “(ii) LAST YEAR OF CONTRACT.—In
10 the case of the last year of a contract
11 under this part, the Secretary may require
12 that a report described in subparagraph
13 (A) be submitted 3 months prior to the
14 end of the contract. Such report shall con-
15 tain information concerning the benefits
16 provided between the period covered by the
17 most recent report under this subpara-
18 graph and the date that a report is sub-
19 mitted under this clause.

20 “(C) CONFIDENTIALITY OF INFORMA-
21 TION.—

22 “(i) IN GENERAL.—Notwithstanding
23 any other provision of law and subject to
24 clause (ii), information disclosed by an eli-
25 gible entity pursuant to subparagraph (A)

1 (except for information described in clause
2 (ii) of such subparagraph) is confidential
3 and shall only be used by the Secretary for
4 the purposes of, and to the extent nec-
5 essary, to carry out this part.

6 “(ii) UTILIZATION DATA.—Subject to
7 patient confidentiality laws, the Secretary
8 shall make information disclosed by an eli-
9 gible entity pursuant to subparagraph
10 (A)(iv) (regarding utilization data) avail-
11 able for research purposes. The Secretary
12 may charge a reasonable fee for making
13 such information available.

14 “(7) APPROVAL OF MARKETING MATERIAL AND
15 APPLICATION FORMS.—The eligible entity complies
16 with the requirements described in section 1860G(f).

17 “(8) RECORDS AND AUDITS.—The eligible enti-
18 ty maintains adequate records related to the man-
19 agement, administration, and delivery of the benefits
20 under this part and affords the Secretary access to
21 such records for auditing purposes.

22 “(b) SPECIAL RULES REGARDING COST-EFFECTIVE
23 PROVISION OF BENEFITS.—

1 “(1) IN GENERAL.—In providing the benefits
2 under a contract under this part, an eligible entity
3 shall—

4 “(A) employ mechanisms to provide the
5 benefits economically, that may include the use
6 of—

7 “(i) alternative methods of distribu-
8 tion;

9 “(ii) preferred pharmacy networks
10 (pursuant to subsection (e)); and

11 “(iii) generic drug substitution;

12 “(B) use mechanisms to encourage eligible
13 beneficiaries to select cost-effective drugs or less
14 costly means of receiving drugs, that may in-
15 clude the use of—

16 “(i) pharmacy incentive programs;

17 “(ii) therapeutic interchange pro-
18 grams; and

19 “(iii) disease management programs;

20 “(C) encourage pharmacy providers to—

21 “(i) inform beneficiaries of the dif-
22 ferentials in price between generic and
23 brand name drug equivalents; and

24 “(ii) provide medication therapy man-
25 agement programs in order to enhance

1 beneficiaries’ understanding of the appro-
 2 priate use of medications and to reduce the
 3 risk of potential adverse events associated
 4 with medications; and

5 “(D) develop and implement a formulary
 6 in accordance with subsection (c).

7 “(2) RESTRICTION.—If an eligible entity uses
 8 alternative methods of distribution pursuant to para-
 9 graph (1)(A)(i), the entity may not require that a
 10 beneficiary use such methods in order to obtain cov-
 11 ered outpatient drugs.

12 “(c) REQUIREMENTS FOR FORMULARIES.—

13 “(1) STANDARDS.—

14 “(A) IN GENERAL.—The formulary devel-
 15 oped and implemented by the eligible entity
 16 shall comply with standards established by the
 17 Secretary in consultation with the Medicare
 18 Prescription Drug Advisory Committee estab-
 19 lished under section 1860L.

20 “(B) NO NATIONAL FORMULARY OR RE-
 21 QUIREMENT TO EXCLUDE SPECIFIC DRUGS.—

22 “(i) SECRETARY MAY NOT ESTABLISH
 23 A NATIONAL FORMULARY.—The Secretary
 24 may not establish a national formulary.

1 “(ii) NO REQUIREMENT TO EXCLUDE
 2 SPECIFIC DRUGS.—The standards estab-
 3 lished by the Secretary pursuant to sub-
 4 paragraph (A) may not require that an eli-
 5 gible entity exclude a specific covered out-
 6 patient drug from the formulary developed
 7 and implemented by the entity.

8 “(2) REQUIREMENTS FOR STANDARDS.—The
 9 standards established under paragraph (1) shall re-
 10 quire that the eligible entity—

11 “(A) use a pharmacy and therapeutic com-
 12 mittee (that meets the standards for a phar-
 13 macy and therapeutic committee established by
 14 the Secretary in consultation with such Medi-
 15 care Prescription Drug Advisory Committee) to
 16 develop and implement the formulary;

17 “(B) include—

18 “(i) all generic covered outpatient
 19 drugs on the formulary;

20 “(ii) at least 1 brand name drug from
 21 each therapeutic class (as defined by the
 22 entity’s pharmacy and therapeutic com-
 23 mittee in accordance with standards estab-
 24 lished by the Secretary in consultation with
 25 the Medicare Pharmacy and Therapeutics

1 Advisory Committee) on the formulary;

2 and

3 “(iii) if there is more than 1 brand
4 name drug available in a therapeutic class,
5 at least 2 brand name drugs from such
6 class on the formulary; and

7 “(C) develop procedures for the modifica-
8 tion of the formulary, including for the addition
9 of new drugs to an existing therapeutic class;

10 “(D) pursuant to section 1860F(b)(3),
11 provide for coverage of nonformulary drugs at
12 the formulary drug rate when determined under
13 subparagraph (D) or (E) of subsection (a)(3) to
14 be medically necessary;

15 “(E) disclose to current and prospective
16 beneficiaries and to providers in the service
17 area the nature of the formulary restrictions,
18 including information regarding the drugs in-
19 cluded on the formulary and any difference in
20 the cost-sharing for—

21 “(i) drugs included on the formulary;

22 and

23 “(ii) for drugs not included on the
24 formulary; and

1 “(F) provide a reasonable amount of notice
 2 to beneficiaries enrolled in the plan that is cov-
 3 ered by the contract under this part of any
 4 change on the formulary.

5 “(3) CONSTRUCTION.—Nothing in this part
 6 shall be construed as precluding an eligible entity
 7 from—

8 “(A) educating prescribing providers, phar-
 9 macists, and beneficiaries about the medical
 10 and cost benefits of drugs included on the for-
 11 mulary for the plan (including generic drugs);
 12 or

13 “(B) requesting prescribing providers to
 14 consider a drug included on the formulary prior
 15 to dispensing of a drug not so included, as long
 16 as such a request does not unduly delay the
 17 provision of the drug.

18 “(d) TERMS OF PARTICIPATION AGREEMENT WITH
 19 PHARMACIES.—

20 “(1) IN GENERAL.—A participation agreement
 21 between an eligible entity and a pharmacy under this
 22 part (pursuant to subsection (a)(3)(A)(ii)) shall in-
 23 clude the following terms and conditions:

24 “(A) APPLICABLE REQUIREMENTS.—The
 25 pharmacy shall meet (and throughout the con-

tract period continue to meet) all applicable Federal requirements and State and local licensing requirements.

“(B) ACCESS AND QUALITY STANDARDS.—

The pharmacy shall comply with such standards as the Secretary (and the eligible entity) shall establish concerning the quality of, and enrolled beneficiaries’ access to, pharmacy services under this part. Such standards shall require the pharmacy—

“(i) not to refuse to dispense covered outpatient drugs to any eligible beneficiary enrolled under this part;

“(ii) to keep patient records (including records on expenses) for all covered outpatient drugs dispensed to such enrolled beneficiaries;

“(iii) to submit information (in a manner specified by the Secretary to be necessary to administer this part) on all purchases of such drugs dispensed to such enrolled beneficiaries; and

“(iv) to comply with periodic audits to assure compliance with the requirements of

1 this part and the accuracy of information
2 submitted.

3 “(C) ENSURING THAT BENEFICIARIES ARE
4 NOT OVERCHARGED.—

5 “(i) ADHERENCE TO NEGOTIATED
6 PRICES.—The total charge for each cov-
7 ered outpatient drug dispensed by the
8 pharmacy to a beneficiary enrolled in the
9 plan, without regard to whether the indi-
10 vidual is financially responsible for any or
11 all of such charge, shall not exceed the ne-
12 gotiated price for the drug (as reported to
13 the Secretary pursuant to subsection
14 (a)(6)(A)).

15 “(ii) ADHERENCE TO BENEFICIARY
16 OBLIGATION.—The pharmacy may not
17 charge (or collect from) such beneficiary
18 an amount that exceeds the cost-sharing
19 that the beneficiary is responsible for
20 under this part (as determined under sec-
21 tion 1860F(b) using the negotiated price
22 of the drug).

23 “(D) ADDITIONAL REQUIREMENTS.—The
24 pharmacy shall meet such additional contract

1 requirements as the eligible entity specifies
2 under this section.

3 “(2) APPLICABILITY OF FRAUD AND ABUSE
4 PROVISIONS.—The provisions of section 1128
5 through 1128C (relating to fraud and abuse) apply
6 to pharmacies participating in the program under
7 this part.

8 “(e) PREFERRED PHARMACY NETWORKS.—

9 “(1) IN GENERAL.—If an eligible entity uses a
10 preferred pharmacy network to deliver benefits
11 under this part, such network shall meet minimum
12 access standards established by the Secretary.

13 “(2) STANDARDS.—In establishing standards
14 under paragraph (1), the Secretary shall take into
15 account reasonable distances to pharmacy services in
16 both urban and rural areas. Such standards shall be
17 consistent with the requirements of this part.

18 “PAYMENTS

19 “SEC. 1860I. (a) PROCEDURES FOR PAYMENTS TO
20 ELIGIBLE ENTITIES.—The Secretary shall establish pro-
21 cedures for making payments to each eligible entity with
22 a contract to offer a plan under this part for the manage-
23 ment, administration, and delivery of the benefits under
24 the plan.

25 “(b) REQUIREMENTS FOR PROCEDURES.—

1 “(1) IN GENERAL.—The procedures established
2 under subsection (a) shall provide for the following:

3 “(A) MANAGEMENT PAYMENT.—Payment
4 for the management, administration, and deliv-
5 ery of the benefits under the plan.

6 “(B) REIMBURSEMENT FOR NEGOTIATED
7 COSTS OF DRUGS PROVIDED.—Payments for the
8 negotiated costs of covered outpatient drugs
9 provided to eligible beneficiaries enrolled under
10 this part and in the plan, reduced by any appli-
11 cable cost-sharing under section 1860F(b).

12 “(C) RISK REQUIREMENT TO ENSURE PUR-
13 SUIT OF PERFORMANCE REQUIREMENTS.—An
14 adjustment of a percentage (as determined
15 under paragraph (2)) of the payments made to
16 an entity under subparagraph (A) to ensure
17 that the entity, in managing, administering,
18 and delivering the benefits under this part, pur-
19 sues performance requirements established by
20 the Secretary, including the following:

21 “(i) CONTROL OF MEDICARE AND
22 BENEFICIARY COSTS.—The entity contains
23 costs to the Prescription Drug Account
24 and to eligible beneficiaries enrolled under
25 this part and in the plan offered by the en-

1 tity, as measured by generic substitution
2 rates, price discounts, and other factors
3 determined appropriate by the Secretary
4 that do not reduce the access of such bene-
5 ficiaries to medically necessary covered
6 outpatient drugs.

7 “(ii) QUALITY CLINICAL CARE.—The
8 entity provides such beneficiaries with
9 quality clinical care, as measured by such
10 factors as—

11 “(I) the level of adverse drug re-
12 actions and medical errors among
13 such beneficiaries; and

14 “(II) providing specific clinical
15 suggestions to improve health and pa-
16 tient and prescriber education as ap-
17 propriate.

18 “(iii) QUALITY SERVICE.—The entity
19 provides such beneficiaries with quality
20 services, as measured by such factors as
21 sustained pharmacy network access, timeli-
22 ness and accuracy of service delivery in
23 claims processing and card production,
24 pharmacy and member service support ac-
25 cess, response time in mail delivery service,

1 and timely action with regard to appeals
2 and current beneficiary service surveys.

3 “(2) PERCENTAGE OF PAYMENT TIED TO
4 RISK.—

5 “(A) IN GENERAL.—Subject to subpara-
6 graph (B), the Secretary shall determine the
7 percentage (which may be up to 100 percent) of
8 the payments made to an entity under para-
9 graph (1)(A) that will be tied to the perform-
10 ance requirements described in paragraph
11 (1)(C).

12 “(B) LIMITATION ON RISK TO ENSURE
13 PROGRAM STABILITY.—In order to provide for
14 program stability, the Secretary may not estab-
15 lish a percentage to be adjusted under this sub-
16 section at a level that jeopardizes the ability of
17 an eligible entity to administer and deliver the
18 benefits under this part or administer and de-
19 liver such benefits in a quality manner.

20 “(3) RISK ADJUSTMENT OF PAYMENTS BASED
21 ON ENROLLEES IN PLAN.—To the extent that an eli-
22 gible entity is at risk under this subsection, the pro-
23 cedures established under subsection (a) may include
24 a methodology for risk adjusting the payments made
25 to such entity based on the differences in actuarial

1 risk of different enrollees being served if the Sec-
2 retary determines such adjustments to be necessary
3 and appropriate.

4 “(4) PASS-THROUGH OF REBATES, DISCOUNTS,
5 AND PRICE CONCESSIONS OBTAINED BY THE ELIGI-
6 BLE ENTITY.—The Secretary shall establish proce-
7 dures for reducing the amount of payments to an el-
8 igible entity under paragraph (1) to take into ac-
9 count any rebates, discounts, or price concessions
10 obtained by the entity from manufacturers of cov-
11 ered outpatient drugs, unless the Secretary deter-
12 mines that such procedures are not in the best inter-
13 ests of the medicare program or eligible bene-
14 ficiaries.

15 “(c) PAYMENTS TO MEDICARE+CHOICE ORGANIZA-
16 TIONS.—For provisions related to payments to
17 Medicare+Choice organizations for the management, ad-
18 ministration, and delivery of benefits under this part to
19 eligible beneficiaries enrolled in a Medicare+Choice plan
20 offered by the organization, see section 1853(c)(8).

21 “(d) SECONDARY PAYER PROVISIONS.—The provi-
22 sions of section 1862(b) shall apply to the benefits pro-
23 vided under this part.

1 “EMPLOYER INCENTIVE PROGRAM FOR EMPLOYMENT-
2 BASED RETIREE DRUG COVERAGE

3 “SEC. 1860J. (a) PROGRAM AUTHORITY.—The Sec-
4 retary is authorized to develop and implement a program
5 under this section to be known as the ‘Employer Incentive
6 Program’ that encourages employers and other sponsors
7 of employment-based health care coverage to provide ade-
8 quate prescription drug benefits to retired individuals by
9 subsidizing, in part, the sponsor’s cost of providing cov-
10 erage under qualifying plans.

11 “(b) SPONSOR REQUIREMENTS.—In order to be eligi-
12 ble to receive an incentive payment under this section with
13 respect to coverage of an individual under a qualified re-
14 tiree prescription drug plan (as defined in subsection
15 (e)(3)), a sponsor shall meet the following requirements:

16 “(1) ASSURANCES.—The sponsor shall—

17 “(A) annually attest, and provide such as-
18 surances as the Secretary may require, that the
19 coverage offered by the sponsor is a qualified
20 retiree prescription drug plan, and will remain
21 such a plan for the duration of the sponsor’s
22 participation in the program under this section;
23 and

24 “(B) guarantee that it will give notice to
25 the Secretary and covered retirees—

1 “(i) at least 120 days before termi-
2 nating its plan; and

3 “(ii) immediately upon determining
4 that the actuarial value of the prescription
5 drug benefit under the plan falls below the
6 actuarial value of the outpatient prescrip-
7 tion drug benefit under this part.

8 “(2) BENEFICIARY INFORMATION.—The spon-
9 sor shall report to the Secretary, for each calendar
10 quarter for which it seeks an incentive payment
11 under this section, the names and social security
12 numbers of all retirees (and their spouses and de-
13 pendents) covered under such plan during such
14 quarter and the dates (if less than the full quarter)
15 during which each such individual was covered.

16 “(3) AUDITS.—The sponsor and the employ-
17 ment-based retiree health coverage plan seeking in-
18 centive payments under this section shall agree to
19 maintain, and to afford the Secretary access to, such
20 records as the Secretary may require for purposes of
21 audits and other oversight activities necessary to en-
22 sure the adequacy of prescription drug coverage, the
23 accuracy of incentive payments made, and such
24 other matters as may be appropriate.

1 “(4) OTHER REQUIREMENTS.—The sponsor
 2 shall provide such other information, and comply
 3 with such other requirements, as the Secretary may
 4 find necessary to administer the program under this
 5 section.

6 “(c) INCENTIVE PAYMENTS.—

7 “(1) IN GENERAL.—A sponsor that meets the
 8 requirements of subsection (b) with respect to a
 9 quarter in a calendar year shall be entitled to have
 10 payment made by the Secretary on a quarterly basis
 11 (to the sponsor or, at the sponsor’s direction, to the
 12 appropriate employment-based health plan) of an in-
 13 centive payment, in the amount determined in para-
 14 graph (2), for each retired individual (or spouse or
 15 dependent) who—

16 “(A) was covered under the sponsor’s
 17 qualified retiree prescription drug plan during
 18 such quarter; and

19 “(B) was eligible for, but was not enrolled
 20 in, the outpatient prescription drug benefit pro-
 21 gram under this part.

22 “(2) AMOUNT OF PAYMENT.—

23 “(A) IN GENERAL.—The amount of the
 24 payment for a quarter shall be, for each indi-
 25 vidual described in paragraph (1), $\frac{2}{3}$ of the

1 sum of the monthly Government contribution
 2 amounts (computed under subparagraph (B))
 3 for each of the 3 months in the quarter.

4 “(B) COMPUTATION OF MONTHLY GOV-
 5 ERNMENT CONTRIBUTION AMOUNT.—For pur-
 6 poses of subparagraph (A), the monthly Gov-
 7 ernment contribution amount for a month in a
 8 year is equal to the amount by which—

9 “(i) $\frac{1}{12}$ of the amount estimated
 10 under subparagraph (C) for the year in-
 11 volved; exceeds

12 “(ii) the monthly Part D premium
 13 under section 1860E(a) (determined with-
 14 out regard to any increase under section
 15 1860B(b)(1)) for the month involved.

16 “(C) ESTIMATE OF AVERAGE ANNUAL PER
 17 CAPITA AGGREGATE EXPENDITURES.—

18 “(i) IN GENERAL.—The Secretary
 19 shall for each year after the period de-
 20 scribed in section 1860E(a)(2)(A), esti-
 21 mate for that year an amount equal to the
 22 average annual per capita aggregate ex-
 23 penditures payable from the Prescription
 24 Drug Account for that year.

1 “(ii) TIMEFRAME FOR ESTIMATION.—

2 The Secretary shall make the estimate de-
3 scribed in clause (i) for a year before the
4 beginning of that year.

5 “(3) PAYMENT DATE.—The payment under this
6 section with respect to a calendar quarter shall be
7 payable as of the end of the next succeeding cal-
8 endar quarter.

9 “(d) CIVIL MONEY PENALTIES.—A sponsor, health
10 plan, or other entity that the Secretary determines has,
11 directly or through its agent, provided information in con-
12 nection with a request for an incentive payment under this
13 section that the entity knew or should have known to be
14 false shall be subject to a civil monetary penalty in an
15 amount up to 3 times the total incentive amounts under
16 subsection (c) that were paid (or would have been payable)
17 on the basis of such information.

18 “(e) DEFINITIONS.—In this section:

19 “(1) EMPLOYMENT-BASED RETIREE HEALTH
20 COVERAGE.—The term ‘employment-based retiree
21 health coverage’ means health insurance or other
22 coverage, whether provided by voluntary insurance
23 coverage or pursuant to statutory or contractual ob-
24 ligation, of health care costs for retired individuals
25 (or for such individuals and their spouses and de-

pendents) based on their status as former employees or labor union members.

“(2) EMPLOYER.—The term ‘employer’ has the meaning given the term in section 3(5) of the Employee Retirement Income Security Act of 1974 (except that such term shall include only employers of 2 or more employees).

“(3) QUALIFIED RETIREE PRESCRIPTION DRUG PLAN.—The term ‘qualified retiree prescription drug plan’ means health insurance coverage included in employment-based retiree health coverage that—

“(A) provides coverage of the cost of prescription drugs with an actuarial value (as defined by the Secretary) to each retired beneficiary that equals or exceeds the actuarial value of the benefits provided to an individual enrolled in the outpatient prescription drug benefit program under this part; and

“(B) does not deny, limit, or condition the coverage or provision of prescription drug benefits for retired individuals based on age or any health status-related factor described in section 2702(a)(1) of the Public Health Service Act.

“(4) SPONSOR.—The term ‘sponsor’ has the meaning given the term ‘plan sponsor’ in section

1 3(16)(B) of the Employer Retirement Income Secu-
2 rity Act of 1974.

3 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
4 are authorized to be appropriated from time to time, out
5 of any moneys in the Treasury not otherwise appropriated,
6 such sums as may be necessary to carry out the program
7 under this section.

8 “PRESCRIPTION DRUG ACCOUNT IN THE FEDERAL
9 SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND

10 “SEC. 1860K. (a) ESTABLISHMENT.—

11 “(1) IN GENERAL.—There is created within the
12 Federal Supplementary Medical Insurance Trust
13 Fund established by section 1841 an account to be
14 known as the ‘Prescription Drug Account’ (in this
15 section referred to as the ‘Account’).

16 “(2) FUNDS.—The Account shall consist of
17 such gifts and bequests as may be made as provided
18 in section 201(i)(1), and such amounts as may be
19 deposited in, or appropriated to, the account as pro-
20 vided in this part.

21 “(3) SEPARATE FROM REST OF TRUST FUND.—
22 Funds provided under this part to the Account shall
23 be kept separate from all other funds within the
24 Federal Supplementary Medical Insurance Trust
25 Fund.

26 “(b) PAYMENTS FROM ACCOUNT.—

1 “(1) IN GENERAL.—The Managing Trustee
 2 shall pay from time to time from the Account such
 3 amounts as the Secretary certifies are necessary to
 4 make payments to operate the program under this
 5 part, including payments to eligible entities under
 6 section 1860I, payments to Medicare+Choice orga-
 7 nizations under section 1853(c)(8), and payments
 8 with respect to administrative expenses under this
 9 part in accordance with section 201(g).

10 “(2) TREATMENT IN RELATION TO PART B PRE-
 11 MIUM.—Amounts payable from the Account shall not
 12 be taken into account in computing actuarial rates
 13 or premium amounts under section 1839.

14 “(c) APPROPRIATIONS TO COVER BENEFITS AND
 15 ADMINISTRATIVE COSTS.—There are appropriated to the
 16 Account in a fiscal year, out of any moneys in the Treas-
 17 ury not otherwise appropriated, an amount equal to the
 18 amount by which the benefits and administrative costs of
 19 providing the benefits under this part in the year exceed
 20 the premiums collected under section 1860E(b) for the
 21 year.

22 “MEDICARE PRESCRIPTION DRUG ADVISORY COMMITTEE
 23 “SEC. 1860L. (a) ESTABLISHMENT OF COM-
 24 MITTEE.—There is established a Medicare Prescription
 25 Drug Advisory Committee (in this section referred to as
 26 the ‘Committee’).

1 “(b) FUNCTIONS OF COMMITTEE.—The Committee
2 shall advise the Secretary on policies related to—

3 “(1) the development of guidelines for the im-
4 plementation and administration of the outpatient
5 prescription drug benefit program under this part;
6 and

7 “(2) the development of—

8 “(A) standards for a pharmacy and thera-
9 peutics committee required of eligible entities
10 under section 1860H(c)(2)(A);

11 “(B) standards required under subpara-
12 graphs (D) and (E) of section 1860H(a)(4) for
13 determining if a drug is medically necessary;

14 “(C) standards for—

15 “(i) establishing therapeutic classes;
16 and

17 “(ii) adding new therapeutic classes to
18 a formulary;

19 “(D) procedures to evaluate the bids sub-
20 mitted by eligible entities under this part; and

21 “(E) procedures to ensure that eligible en-
22 tities with a contract under this part are in
23 compliance with the requirements under this
24 part.

1 “(c) STRUCTURE AND MEMBERSHIP OF THE COM-
2 MITTEE.—

3 “(1) STRUCTURE.—The Committee shall be
4 composed of 19 members who shall be appointed by
5 the Secretary as soon as possible after the date of
6 enactment of the Prescription Drug Benefit and
7 Cost Containment Act of 2003.

8 “(2) MEMBERSHIP.—

9 “(A) IN GENERAL.—The members of the
10 Committee shall be chosen on the basis of their
11 integrity, impartiality, and good judgment, and
12 shall be individuals who are, by reason of their
13 education, experience, attainments, and under-
14 standing of pharmaceutical cost control and
15 quality enhancement, exceptionally qualified to
16 perform the duties of members of the Com-
17 mittee.

18 “(B) SPECIFIC MEMBERS.—Of the mem-
19 bers appointed under paragraph (1)—

20 “(i) five shall be chosen to represent
21 physicians, 2 of whom shall be geriatri-
22 cians;

23 “(ii) two shall be chosen to represent
24 nurse practitioners;

1 “(iii) four shall be chosen to represent
2 pharmacists;

3 “(iv) one shall be chosen to represent
4 the Centers for Medicare & Medicaid Serv-
5 ices;

6 “(v) four shall be chosen to represent
7 actuaries, pharmacoeconomists, research-
8 ers, and other appropriate experts;

9 “(vi) one shall be chosen to represent
10 emerging drug technologies;

11 “(vii) one shall be chosen to represent
12 the Food and Drug Administration; and

13 “(viii) one shall be chosen to represent
14 individuals enrolled under this part.

15 “(d) CHAIRPERSON.—The Secretary shall designate
16 a member of the Committee as Chairperson. The term as
17 Chairperson shall be for a 1-year period.

18 “(e) COMMITTEE PERSONNEL MATTERS.—

19 “(1) MEMBERS.—

20 “(A) COMPENSATION.—Each member of
21 the Committee who is not an officer or em-
22 ployee of the Federal Government shall be com-
23 pensated at a rate equal to the daily equivalent
24 of the annual rate of basic pay prescribed for
25 level IV of the Executive Schedule under section

1 5315 of title 5, United States Code, for each
 2 day (including travel time) during which such
 3 member is engaged in the performance of the
 4 duties of the Committee. All members of the
 5 Committee who are officers or employees of the
 6 United States shall serve without compensation
 7 in addition to that received for their services as
 8 officers or employees of the United States.

9 “(B) TRAVEL EXPENSES.—The members
 10 of the Committee shall be allowed travel ex-
 11 penses, including per diem in lieu of subsist-
 12 ence, at rates authorized for employees of agen-
 13 cies under subchapter I of chapter 57 of title 5,
 14 United States Code, while away from their
 15 homes or regular places of business in the per-
 16 formance of services for the Committee.

17 “(2) STAFF.—The Committee may appoint
 18 such personnel as the Committee considers appro-
 19 priate.

20 “(f) OPERATION OF THE COMMITTEE.—

21 “(1) MEETINGS.—The Committee shall meet at
 22 the call of the Chairperson (after consultation with
 23 the other members of the Committee) not less often
 24 than quarterly to consider a specific agenda of

1 issues, as determined by the Chairperson after such
2 consultation.

3 “(2) QUORUM.—Ten members of the Com-
4 mittee shall constitute a quorum for purposes of
5 conducting business.

6 “(g) FEDERAL ADVISORY COMMITTEE ACT.—Section
7 14 of the Federal Advisory Committee Act (5 U.S.C.
8 App.) shall not apply to the Committee.

9 “(h) TRANSFER OF PERSONNEL, RESOURCES, AND
10 ASSETS.—For purposes of carrying out its duties, the Sec-
11 retary and the Committee may provide for the transfer
12 to the Committee of such civil service personnel in the em-
13 ploy of the Department of Health and Human Services
14 (including the Centers for Medicare & Medicaid Services),
15 and such resources and assets of the Department used in
16 carrying out this title, as the Committee requires.

17 “(i) AUTHORIZATION OF APPROPRIATIONS.—There
18 are authorized to be appropriated such sums as may be
19 necessary to carry out the purposes of this section.”.

20 (b) EXCLUSIONS FROM COVERAGE.—

21 (1) APPLICATION TO PART D.—Section 1862(a)
22 of the Social Security Act (42 U.S.C. 1395y(a)) is
23 amended in the matter preceding paragraph (1) by
24 striking “part A or part B” and inserting “part A,
25 B, or D”.

1 (2) PRESCRIPTION DRUGS NOT EXCLUDED
 2 FROM COVERAGE IF REASONABLE AND NEC-
 3 ESSARY.—Section 1862(a)(1) of the Social Security
 4 Act (42 U.S.C. 1395y(a)(1)) is amended—

5 (A) in subparagraph (H), by striking
 6 “and” at the end;

7 (B) in subparagraph (I), by striking the
 8 semicolon at the end and inserting “, and”; and

9 (C) by adding at the end the following new
 10 subparagraph:

11 “(J) in the case of prescription drugs cov-
 12 ered under part D, which are not reasonable
 13 and necessary to prevent or slow the deteriora-
 14 tion of, or improve or maintain, the health of
 15 eligible beneficiaries;”.

16 (c) CONFORMING AMENDMENTS TO FEDERAL SUP-
 17 PLEMENTARY MEDICAL INSURANCE TRUST FUND.—Sec-
 18 tion 1841 of the Social Security Act (42 U.S.C. 1395t)
 19 is amended—

20 (1) in the last sentence of subsection (a)—

21 (A) by striking “and” before “such
 22 amounts”; and

23 (B) by inserting before the period the fol-
 24 lowing: “, and such amounts as may be depos-

1 ited in, or appropriated to, the Prescription
2 Drug Account established by section 1860K”;

3 (2) in subsection (g), by inserting after “by this
4 part,” the following: “the payments provided for
5 under part D (in which case the payments shall be
6 made from the Prescription Drug Account in the
7 Trust Fund),”;

8 (3) in subsection (h), by inserting after
9 “1840(d)” the following: “and section 1860E(b) (in
10 which case the payments shall be made from the
11 Prescription Drug Account in the Trust Fund)”;
12 and

13 (4) in subsection (i), by inserting after “section
14 1840(b)(1)” the following: “, section 1860E(b) (in
15 which case the payments shall be made from the
16 Prescription Drug Account in the Trust Fund),”.

17 (d) CONFORMING REFERENCES TO PREVIOUS PART
18 D.—

19 (1) IN GENERAL.—Any reference in law (in ef-
20 fect before the date of enactment of this Act) to part
21 D of title XVIII of the Social Security Act is deemed
22 a reference to part E of such title (as in effect after
23 such date).

24 (2) SECRETARIAL SUBMISSION OF LEGISLATIVE
25 PROPOSAL.—Not later than 6 months after the date

1 of enactment of this Act, the Secretary of Health
 2 and Human Services shall submit to Congress a leg-
 3 islative proposal providing for such technical and
 4 conforming amendments in the law as are required
 5 by the provisions of this title.

6 **SEC. 102. PART D BENEFITS UNDER MEDICARE+CHOICE**
 7 **PLANS.**

8 (a) **ELIGIBILITY, ELECTION, AND ENROLLMENT.**—
 9 Section 1851 of the Social Security Act (42 U.S.C.
 10 1395w–21) is amended—

11 (1) in subsection (a)(1)(A), by striking “parts
 12 A and B” and inserting “parts A, B, and D”; and

13 (2) in subsection (i)(1), by striking “parts A
 14 and B” and inserting “parts A, B, and D”.

15 (b) **VOLUNTARY BENEFICIARY ENROLLMENT FOR**
 16 **DRUG COVERAGE.**—Section 1852(a)(1)(A) of the Social
 17 Security Act (42 U.S.C. 1395w–22(a)(1)(A)) is amended
 18 by inserting “(and under part D to individuals also en-
 19 rolled under that part)” after “parts A and B”.

20 (c) **ACCESS TO SERVICES.**—Section 1852(d)(1) of the
 21 Social Security Act (42 U.S.C. 1395w–22(d)(1)) is
 22 amended—

23 (1) in subparagraph (D), by striking “and” at
 24 the end;

1 (2) in subparagraph (E), by striking the period
2 at the end and inserting “; and”; and

3 (3) by adding at the end the following new sub-
4 paragraph:

5 “(F) in the case of covered outpatient
6 drugs (as defined in section 1860(1)) provided
7 to individuals enrolled under part D, the orga-
8 nization complies with the access requirements
9 applicable under part D.”.

10 (d) PAYMENTS TO ORGANIZATIONS FOR PART D
11 BENEFITS.—

12 (1) IN GENERAL.—Section 1853(a)(1)(A) of the
13 Social Security Act (42 U.S.C. 1395w–23(a)(1)(A))
14 is amended—

15 (A) by inserting “determined separately for
16 the benefits under parts A and B and under
17 part D (for individuals enrolled under that
18 part)” after “as calculated under subsection
19 (c)”;

20 (B) by striking “that area, adjusted for
21 such risk factors” and inserting “that area. In
22 the case of payment for the benefits under
23 parts A and B, such payment shall be adjusted
24 for such risk factors as”; and

1 (C) by inserting before the last sentence
 2 the following: “In the case of the payments
 3 under subsection (c)(8) for the provision of cov-
 4 erage of covered outpatient drugs to individuals
 5 enrolled under part D, such payment shall be
 6 adjusted for the risk factors of each enrollee as
 7 the Secretary determines to be feasible and ap-
 8 propriate to ensure actuarial equivalence.”.

9 (2) AMOUNT.—Section 1853(c) of the Social
 10 Security Act (42 U.S.C. 1395w–23(c)) is amended—

11 (A) in paragraph (1), in the matter pre-
 12 ceding subparagraph (A), by inserting “for ben-
 13 efits under parts A and B” after “capitation
 14 rate”; and

15 (B) by adding at the end the following new
 16 paragraph:

17 “(8) CAPITATION RATE FOR PART D BENE-
 18 FITS.—

19 “(A) IN GENERAL.—In the case of a
 20 Medicare+Choice plan that provides coverage
 21 of covered outpatient drugs to an individual en-
 22 rolled under part D, the capitation rate for
 23 such coverage shall be the amount described in
 24 subparagraph (B). Such payments shall be
 25 made in the same manner and at the same time

as the payments to the Medicare+Choice organization offering the plan for benefits under parts A and B are otherwise made, but such payments shall be payable from the Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund under section 1841.

“(B) AMOUNT.—The amount described in this paragraph is an amount equal to $\frac{1}{12}$ of the average annual per capita aggregate expenditures payable from the Prescription Drug Account for the year (as estimated under section 1860J(c)(2)(C)).”.

(e) LIMITATION ON ENROLLEE LIABILITY.—Section 1854(e) of the Social Security Act (42 U.S.C. 1395w-24(e)) is amended by adding at the end the following new paragraph:

“(5) SPECIAL RULE FOR PART D BENEFITS.—

With respect to outpatient prescription drug benefits under part D, a Medicare+Choice organization may not require that an enrollee pay any deductible or pay a cost-sharing amount that exceeds the amount of cost-sharing applicable for such benefits for an eligible beneficiary under part D.”.

1 (f) REQUIREMENT FOR ADDITIONAL BENEFITS.—
 2 Section 1854(f)(1) of the Social Security Act (42 U.S.C.
 3 1395w–24(f)(1)) is amended by adding at the end the fol-
 4 lowing new sentence: “Such determination shall be made
 5 separately for the benefits under parts A and B and for
 6 prescription drug benefits under part D.”.

7 (g) EFFECTIVE DATE.—The amendments made by
 8 this section shall apply to items and services provided
 9 under a Medicare+Choice plan on or after the implemen-
 10 tation date of the Prescription Drug Benefit and Cost
 11 Containment Act of 2003, as determined by the Secretary
 12 of Health and Human Services in accordance with section
 13 1860A(a)(1) of the Social Security Act (as added by sec-
 14 tion 101).

15 **SEC. 103. ADDITIONAL ASSISTANCE FOR LOW-INCOME**
 16 **BENEFICIARIES.**

17 (a) INCLUSION IN MEDICARE COST-SHARING.—Sec-
 18 tion 1905(p)(3) of the Social Security Act (42 U.S.C.
 19 1396d(p)(3)) is amended—

20 (1) in subparagraph (A)—

21 (A) in clause (i), by striking “and” at the
 22 end;

23 (B) in clause (ii), by inserting “and” at
 24 the end; and

1 (C) by adding at the end the following new
 2 clause:

3 “(iii) premiums under section 1860E(a).”; and
 4 (2) in subparagraph (B)—

5 (A) by inserting “(i)” after “(B)”; and

6 (B) by adding at the end the following new
 7 clause:

8 “(ii) Cost-sharing described in section
 9 1860F(b).”.

10 (b) EXPANSION OF MEDICAL ASSISTANCE.—Section
 11 1902(a)(10)(E) of the Social Security Act (42 U.S.C.
 12 1396a(a)(10)(E)) is amended—

13 (1) in clause (iii)—

14 (A) by striking “section 1905(p)(3)(A)(ii)”
 15 and inserting “clauses (ii) and (iii) of section
 16 1905(p)(3)(A) and for medicare cost-sharing
 17 described in section 1905(p)(3)(B)(ii),”; and

18 (B) by striking “and” at the end;

19 (2) by redesignating clause (iv) as clause (vi);

20 and

21 (3) by inserting after clause (iii) the following
 22 new clauses:

23 “(iv) for making medical assistance avail-
 24 able for medicare cost-sharing described in sec-
 25 tion 1905(p)(3)(A)(iii) and for medicare cost-

1 sharing described in section 1905(p)(3)(B)(ii)
 2 for individuals who would be qualified medicare
 3 beneficiaries described in section 1905(p)(1)
 4 but for the fact that their income exceeds 120
 5 percent but does not exceed 135 percent of such
 6 official poverty line for a family of the size in-
 7 volved;

8 “(v) for making medical assistance avail-
 9 able for medicare cost-sharing described in sec-
 10 tion 1905(p)(3)(A)(iii) on a linear sliding scale
 11 based on the income of such individuals for in-
 12 dividuals who would be qualified medicare bene-
 13 ficiaries described in section 1905(p)(1) but for
 14 the fact that their income exceeds 135 percent
 15 but does not exceed 175 percent of such official
 16 poverty line for a family of the size involved;
 17 and”.

18 (c) NONAPPLICABILITY OF RESOURCE REQUIRE-
 19 MENTS TO MEDICARE PART D COST-SHARING.—Section
 20 1905(p)(1) of the Social Security Act (42 U.S.C.
 21 1396d(p)(1)) is amended by adding at the end the fol-
 22 lowing flush sentence:

23 “In determining if an individual is a qualified medicare
 24 beneficiary under this paragraph, subparagraph (C) shall
 25 not be applied for purposes of providing the individual

1 with medicare cost-sharing described in section
 2 1905(p)(3)(A)(iii) or for medicare cost-sharing described
 3 in section 1905(p)(3)(B)(ii).”.

4 (d) NONAPPLICABILITY OF PAYMENT DIFFERENTIAL
 5 REQUIREMENTS TO MEDICARE PART D COST-SHAR-
 6 ING.—Section 1902(n)(2) of the Social Security Act (42
 7 U.S.C. 1396a(n)(2)) is amended by adding at the end the
 8 following new sentence: “The preceding sentence shall not
 9 apply to the cost-sharing described in section 1860F(b).”.

10 (e) INCREASE IN FEDERAL MEDICAL ASSISTANCE
 11 PERCENTAGES FOR ADDITIONAL ASSISTANCE FOR LOW-
 12 INCOME BENEFICIARIES.—

13 (1) IN GENERAL.—The first sentence of section
 14 1905(b) of the Social Security Act (42 U.S.C.
 15 1396d(b)) is amended—

16 (A) by striking “and” before “(4)”; and

17 (B) by inserting before the period at the
 18 end the following: “, and (5) the Federal med-
 19 ical assistance percentage shall be equal to the
 20 Medicare Drug Benefit Low-Income Assistance
 21 percentage (as defined in subsection (x)) with
 22 respect to medical assistance provided for medi-
 23 care cost-sharing described in subparagraph
 24 (A)(iii) or (B)(ii) of subsection (p)(3) and for
 25 administrative expenditures incurred by the

1 State that are attributable to providing such
 2 medicare cost-sharing”.

3 (2) DEFINITION OF MEDICARE DRUG BENEFIT
 4 LOW-INCOME ASSISTANCE PERCENTAGE.—Section
 5 1905 of the Social Security Act (42 U.S.C. 1396d)
 6 is amended by adding at the end the following new
 7 subsection:

8 “(x)(1) For purposes of clause (5) of subsection (b),
 9 and except as provided in paragraph (2), the Medicare
 10 Drug Benefit Low-Income Assistance percentage is 100
 11 percent.

12 “(2) With respect to medicare cost-sharing described
 13 in subparagraph (A)(iii) or (B)(ii) of subsection (p)(3)
 14 provided to individuals eligible for medical assistance
 15 under section 1902(a)(10)(A)(i)(I), 1902(a)(10)(A)(i)(II)
 16 or 1902(f) and administrative expenditures incurred by
 17 the State that are attributable to providing such medicare
 18 cost-sharing to such individuals, the Medicare Drug Ben-
 19 efit Low-Income Assistance percentage for purposes of
 20 clause (5) of subsection (b) shall be equal to the lesser
 21 of—

22 “(A) in the case of fiscal year 2005—

23 “(i) 100 percent; or

24 “(ii) the Federal medical assistance per-
 25 centage determined for the State for fiscal year

1 2005 increased by the number of percentage
 2 points equal to 10 percent of the number of
 3 percentage points by which (I) such Federal
 4 medical assistance percentage for the State is
 5 less than (II) 100 percent; and

6 “(B) in the case of fiscal year 2006 and any
 7 subsequent fiscal year—

8 “(i) 100 percent; or

9 “(ii) the percentage determined under sub-
 10 paragraph (A)(ii) for the previous fiscal year in-
 11 creased by the number of percentage points
 12 equal to 10 percent of the number of percent-
 13 age points by which (I) the Federal medical as-
 14 sistance percentage for the State for fiscal year
 15 2005 is less than (II) 100 percent.”.

16 (f) TREATMENT OF TERRITORIES.—Section 1108(g)
 17 of the Social Security Act (42 U.S.C. 1308(g)) is amended
 18 by adding at the end the following new paragraph:

19 “(3) Notwithstanding the preceding provisions of this
 20 subsection, with respect to fiscal year 2005 and any fiscal
 21 year thereafter, the amount otherwise determined under
 22 this subsection (and subsection (f)) for the fiscal year for
 23 a Commonwealth or territory shall be increased by the
 24 ratio (as estimated by the Secretary) of—

1 “(A) the aggregate amount of payments made
 2 to the 50 States and the District of Columbia for
 3 the fiscal year under title XIX that are attributable
 4 to making medical assistance available for individ-
 5 uals described in clauses (i), (iii), (iv), and (v) of
 6 section 1902(a)(10)(E) for payment of medicare
 7 cost-sharing described in section 1905(p)(3)(A)(iii)
 8 and for medicare cost-sharing described in section
 9 1905(p)(3)(B)(ii); to

10 “(B) the aggregate amount of total payments
 11 made to such States and District for the fiscal year
 12 under such title.”.

13 (g) AMENDMENT TO BEST PRICE.—Section
 14 1927(c)(1)(C)(i) of the Social Security Act (42 U.S.C.
 15 1396r–8(c)(1)(C)(i)) is amended—

16 (1) by striking “and” at the end of subclause
 17 (III);

18 (2) by striking the period at the end of sub-
 19 clause (IV) and inserting “; and”; and

20 (3) by adding at the end the following new sub-
 21 clause:

22 “(V) any prices charged which
 23 are negotiated under a plan under
 24 part D of title XVIII with respect to
 25 covered outpatient drugs, under a

1 Medicare+Choice plan under part C
 2 of such title with respect to such
 3 drugs, or by a qualified retiree pre-
 4 scription drug plan (as defined in sec-
 5 tion 1860J(e)(3)) with respect to such
 6 drugs, on behalf of eligible bene-
 7 ficiaries (as defined in section
 8 1860(2)).”.

9 (h) CONFORMING AMENDMENTS.—Section 1933 of
 10 the Social Security Act (42 U.S.C. 1396u–3) is amend-
 11 ed—

12 (1) in subsection (a), by striking “section
 13 1902(a)(10)(E)(iv)” and inserting “section
 14 1902(a)(10)(E)(vi)”;

15 (2) in subsection (c)(2)(A)—

16 (A) in clause (i), by striking “section
 17 1902(a)(10)(E)(iv)(I)” and inserting “section
 18 1902(a)(10)(E)(vi)(I)”; and

19 (B) in clause (ii), by striking “section
 20 1902(a)(10)(E)(iv)(II)” and inserting “section
 21 1902(a)(10)(E)(vi)(II)”;

22 (3) in subsection (d), by striking “section
 23 1902(a)(10)(E)(iv)” and inserting “section
 24 1902(a)(10)(E)(vi)”;

1 (4) in subsection (e), by striking “section
2 1902(a)(10)(E)(iv)” and inserting “section
3 1902(a)(10)(E)(vi)”.

4 (i) EFFECTIVE DATE.—The amendments made by
5 this section shall apply for medical assistance provided
6 under section 1902(a)(10)(E) of the Social Security Act
7 (42 U.S.C. 1396a(a)(10)(E)) on and after the implemen-
8 tation date of the Prescription Drug Benefit and Cost
9 Containment Act of 2003, as determined by the Secretary
10 of Health and Human Services in accordance with section
11 1860A(a)(1) of the Social Security Act (as added by sec-
12 tion 101).

13 (j) RULE OF CONSTRUCTION.—Nothing in the
14 amendments made by this section shall be construed as
15 precluding a State from using State funds to provide cov-
16 erage of outpatient prescription drugs that is in addition
17 to the coverage of such drugs required under title XIX
18 of the Social Security Act (42 U.S.C. 1396 et seq.), as
19 amended by this section.

20 (k) SENSE OF THE SENATE.—It is the sense of the
21 Senate that during consideration of any conference report
22 for this legislation, conferees should explore ways to pro-
23 vide incentives to States (and in particular to those States
24 that, as of the date of enactment of this Act, offer some
25 form of prescription drug assistance to the elderly and the

1 disabled) to maintain existing State commitments to pro-
 2 vide prescription drug assistance to the elderly and dis-
 3 abled or to supplement the drug benefit established by the
 4 conference report.

5 **SEC. 104. MEDIGAP REVISIONS.**

6 Section 1882 of the Social Security Act (42 U.S.C.
 7 1395ss) is amended by adding at the end the following
 8 new subsection:

9 “(v) MODERNIZED BENEFIT PACKAGES FOR MEDI-
 10 CARE SUPPLEMENTAL POLICIES.—

11 “(1) REVISION OF BENEFIT PACKAGES.—

12 “(A) IN GENERAL.—Notwithstanding sub-
 13 section (p), the benefit packages classified as
 14 ‘H’, ‘I’, and ‘J’ under the standards established
 15 by subsection (p)(2) (including the benefit
 16 package classified as ‘J’ with a high deductible
 17 feature, as described in subsection (p)(11))
 18 shall be revised so that—

19 “(i) the coverage of outpatient pre-
 20 scription drugs available under such ben-
 21 efit packages is replaced with coverage of
 22 outpatient prescription drugs that com-
 23 plements but does not duplicate the cov-
 24 erage of outpatient prescription drugs that
 25 is otherwise available under this title;

1 “(ii) the revised benefit packages pro-
2 vide a range of coverage options for out-
3 patient prescription drugs for beneficiaries,
4 but do not provide coverage for more than
5 90 percent of the cost-sharing amount ap-
6 plicable to an individual under section
7 1860F(b);

8 “(iii) uniform language and defini-
9 tions are used with respect to such revised
10 benefits;

11 “(iv) uniform format is used in the
12 policy with respect to such revised benefits;

13 “(v) such revised standards meet any
14 additional requirements imposed by the
15 amendments made by the Prescription
16 Drug Benefit and Cost Containment Act of
17 2003; and

18 “(vi) except as revised under the pre-
19 ceding clauses or as provided under sub-
20 section (p)(1)(E), the benefit packages are
21 identical to the benefit packages that were
22 available on the date of enactment of the
23 Prescription Drug Benefit and Cost Con-
24 tainment Act of 2003.

1 “(B) MANNER OF REVISION.—The benefit
2 packages revised under this section shall be re-
3 vised in the manner described in subparagraph
4 (E) of subsection (p)(1), except that for pur-
5 poses of subparagraph (C) of such subsection,
6 the standards established under this subsection
7 shall take effect not later than the implementa-
8 tion date of the Prescription Drug Benefit and
9 Cost Containment Act of 2003, as determined
10 by the Secretary of Health and Human Services
11 in accordance with section 1860A(a)(1).

12 “(2) CONSTRUCTION OF BENEFITS IN OTHER
13 MEDICARE SUPPLEMENTAL POLICIES.—Nothing in
14 the benefit packages classified as ‘A’ through ‘G’
15 under the standards established by subsection (p)(2)
16 (including the benefit package classified as ‘F’ with
17 a high deductible feature, as described in subsection
18 (p)(11)) shall be construed as providing coverage for
19 benefits for which payment may be made under part
20 D.

21 “(3) GUARANTEED ISSUANCE AND RENEWAL
22 OF REVISED POLICIES.—The provisions of sub-
23 sections (q) and (s), including provisions of sub-
24 section (s)(3) (relating to special enrollment periods
25 in cases of termination or disenrollment), shall apply

1 to medicare supplemental policies revised under this
 2 subsection in the same manner as such provisions
 3 apply to medicare supplemental policies issued under
 4 the standards established under subsection (p).

5 “(4) OPPORTUNITY OF CURRENT POLICY-
 6 HOLDERS TO PURCHASE REVISED POLICIES.—

7 “(A) IN GENERAL.—No medicare supple-
 8 mental policy of an issuer with a benefit pack-
 9 age that is revised under paragraph (1) shall be
 10 deemed to meet the standards in subsection (c)
 11 unless the issuer—

12 “(i) provides written notice during the
 13 60-day period immediately preceding the
 14 period established for the open enrollment
 15 period established under section
 16 1860B(b)(2), to each individual who is a
 17 policyholder or certificate holder of a medi-
 18 care supplemental policy issued by that
 19 issuer (at the most recent available address
 20 of that individual) of the offer described in
 21 clause (ii) and of the fact that such indi-
 22 vidual will no longer be covered under such
 23 policy as of the implementation date of the
 24 Prescription Drug Benefit and Cost Con-
 25 tainment Act of 2003, as determined by

1 the Secretary of Health and Human Serv-
2 ices in accordance with section
3 1860A(a)(1); and

4 “(ii) offers the policyholder or certifi-
5 cate holder under the terms described in
6 subparagraph (B), during at least the pe-
7 riod established under section
8 1860B(b)(2), a medicare supplemental pol-
9 icy with the benefit package that the Sec-
10 retary determines is most comparable to
11 the policy in which the individual is en-
12 rolled with coverage effective as of the date
13 on which the individual is first entitled to
14 benefits under part D.

15 “(B) TERMS OF OFFER DESCRIBED.—The
16 terms described in this subparagraph are terms
17 which do not—

18 “(i) deny or condition the issuance or
19 effectiveness of a medicare supplemental
20 policy described in subparagraph (A)(ii)
21 that is offered and is available for issuance
22 to new enrollees by such issuer;

23 “(ii) discriminate in the pricing of
24 such policy because of health status, claims

experience, receipt of health care, or medical condition; or

“(iii) impose an exclusion of benefits based on a preexisting condition under such policy.

“(5) PENALTIES.—Each penalty under this section shall apply with respect to policies revised under this subsection as if such policies were issued under the standards established under subsection (p), including the penalties under subsections (a), (d), (p)(8), (p)(9), (q)(5), (r)(6)(A), (s)(4), and (t)(2)(D).”.

SEC. 105. COVERAGE OF IMMUNOSUPPRESSIVE DRUGS FOR ALL MEDICARE BENEFICIARIES UNDER PART B.

(a) COVERAGE REGARDLESS OF WHETHER MEDICARE PAID FOR TRANSPLANT.—Section 1861(s)(2)(J) of the Social Security Act (42 U.S.C. 1395x(s)(2)(J)) is amended by striking “, to an individual who receives” and all that follows before the semicolon at the end and inserting “to an individual who has received an organ transplant”.

(b) CONTINUED ENTITLEMENT TO IMMUNOSUPPRESSIVE DRUGS.—

1 (1) KIDNEY TRANSPLANT RECIPIENTS.—Sec-
 2 tion 226A(b)(2) of the Social Security Act (42
 3 U.S.C. 426–1(b)(2)) is amended by inserting “(ex-
 4 cept for coverage of immunosuppressive drugs under
 5 section 1861(s)(2)(J))” after “shall end”.

6 (2) OTHER TRANSPLANT RECIPIENTS.—The
 7 flush matter following paragraph (2)(C)(ii)(II) of
 8 section 226(b) of the Social Security Act (42 U.S.C.
 9 426(b)) is amended by striking “of this subsection)”
 10 and inserting “of this subsection and except for cov-
 11 erage of immunosuppressive drugs under section
 12 1861(s)(2)(J))”.

13 (3) APPLICATION.—Section 1836 of the Social
 14 Security Act (42 U.S.C. 1395o) is amended—

15 (A) by striking “Every individual who”
 16 and inserting “(a) IN GENERAL.—Every indi-
 17 vidual who”; and

18 (B) by adding at the end the following new
 19 subsection:

20 “(b) SPECIAL RULES APPLICABLE TO INDIVIDUALS
 21 ONLY ELIGIBLE FOR COVERAGE OF IMMUNOSUPPRESSIVE
 22 DRUGS.—

23 “(1) IN GENERAL.—In the case of an individual
 24 whose eligibility for benefits under this title has
 25 ended except for the coverage of immunosuppressive

1 drugs by reason of section 226(b) or 226A(b)(2), the
 2 following rules shall apply:

3 “(A) The individual shall be deemed to be
 4 enrolled under this part for purposes of receiv-
 5 ing coverage of such drugs.

6 “(B) The individual shall be responsible
 7 for the full amount of the premium under sec-
 8 tion 1839 in order to receive such coverage.

9 “(C) The provision of such drugs shall be
 10 subject to the application of—

11 “(i) the deductible under section
 12 1833(b); and

13 “(ii) the coinsurance amount applica-
 14 ble for such drugs (as determined under
 15 this part).

16 “(D) If the individual is an inpatient of a
 17 hospital or other entity, the individual is enti-
 18 tled to receive coverage of such drugs under
 19 this part.

20 “(2) ESTABLISHMENT OF PROCEDURES IN
 21 ORDER TO IMPLEMENT COVERAGE.—The Secretary
 22 shall establish procedures for—

23 “(A) identifying beneficiaries that are enti-
 24 tled to coverage of immunosuppressive drugs by
 25 reason of section 226(b) or 226A(b)(2); and

1 “(B) distinguishing such beneficiaries from
 2 beneficiaries that are enrolled under this part
 3 for the complete package of benefits under this
 4 part.”.

5 (4) TECHNICAL AMENDMENT.—Subsection (c)
 6 of section 226A of the Social Security Act (42
 7 U.S.C. 426–1), as added by section 201(a)(3)(D)(ii)
 8 of the Social Security Independence and Program
 9 Improvements Act of 1994 (Public Law 103–296;
 10 108 Stat. 1497), is redesignated as subsection (d).

11 (c) EXTENSION OF SECONDARY PAYER REQUIRE-
 12 MENTS FOR ESRD BENEFICIARIES.—Section
 13 1862(b)(1)(C) of the Social Security Act (42 U.S.C.
 14 1395y(b)(1)(C)) is amended by adding at the end the fol-
 15 lowing new sentence: “With regard to immunosuppressive
 16 drugs furnished on or after the date of enactment of this
 17 sentence, this subparagraph shall be applied without re-
 18 gard to any time limitation.”.

19 (d) EFFECTIVE DATE.—The amendments made by
 20 this section shall apply to drugs furnished on or after the
 21 date of enactment of this Act.

22 **SEC. 106. HHS STUDY AND REPORT ON UNIFORM PHAR-**
 23 **MACY BENEFIT CARDS.**

24 (a) STUDIES.—The Secretary of Health and Human
 25 Services shall conduct a study to determine the feasibility

1 and advisability of establishing a uniform format for phar-
 2 macy benefit cards provided to beneficiaries by eligible en-
 3 tities under the outpatient prescription drug benefit pro-
 4 gram under part D of title XVIII of the Social Security
 5 Act (as added by section 101).

6 (b) REPORT.—Not later than 2 years after the date
 7 of enactment of this Act, the Secretary of Health and
 8 Human Services shall submit to Congress a report on the
 9 results of the study conducted under subsection (a) to-
 10 gether with any recommendations for legislation that the
 11 Secretary determines to be appropriate as a result of such
 12 study.

13 **SEC. 107. EXPANSION OF MEMBERSHIP AND DUTIES OF**
 14 **MEDICARE PAYMENT ADVISORY COMMISSION**
 15 **(MEDPAC).**

16 (a) EXPANSION OF MEMBERSHIP.—

17 (1) IN GENERAL.—Section 1805(c) of the So-
 18 cial Security Act (42 U.S.C. 1395b–6(c)) is amend-
 19 ed—

20 (A) in paragraph (1), by striking “17” and
 21 inserting “19”; and

22 (B) in paragraph (2)(B), by inserting “ex-
 23 perts in the area of pharmacology and prescrip-
 24 tion drug benefit programs,” after “other
 25 health professionals,”.

1 (2) INITIAL TERMS OF ADDITIONAL MEM-
2 BERS.—

3 (A) IN GENERAL.—For purposes of stag-
4 gering the initial terms of members of the
5 Medicare Payment Advisory Commission under
6 section 1805(c)(3) of the Social Security Act
7 (42 U.S.C. 1395b–6(c)(3)), the initial terms of
8 the 2 additional members of the Commission
9 provided for by the amendment under para-
10 graph (1)(A) are as follows:

11 (i) One member shall be appointed for
12 1 year.

13 (ii) One member shall be appointed
14 for 2 years.

15 (B) COMMENCEMENT OF TERMS.—Such
16 terms shall begin on January 1, 2004.

17 (b) EXPANSION OF DUTIES.—Section 1805(b)(2) of
18 the Social Security Act (42 U.S.C. 1395b–6(b)(2)) is
19 amended by adding at the end the following new subpara-
20 graph:

21 “(D) PRESCRIPTION MEDICINE BENEFIT
22 PROGRAM.—Specifically, the Commission shall
23 review, with respect to the outpatient prescrip-
24 tion drug benefit program under part D, the
25 impact of such program on—

1 “(i) the pharmaceutical market, in-
2 cluding costs and pricing of pharma-
3 ceuticals, beneficiary access to such phar-
4 maceuticals, and trends in research and
5 development;

6 “(ii) franchise, independent, and rural
7 pharmacies; and

8 “(iii) beneficiary access to outpatient
9 prescription drugs, including an assess-
10 ment of out-of-pocket spending, generic
11 and brand name drug utilization, and
12 pharmacists’ services.”.

13 **TITLE II—PRESCRIPTION DRUG**
14 **COST CONTAINMENT AND**
15 **QUALITY ASSURANCE**

16 **SEC. 201. FILING OF PATENT INFORMATION WITH THE**
17 **FOOD AND DRUG ADMINISTRATION.**

18 (a) FILING AFTER APPROVAL OF AN APPLICA-
19 TION.—

20 (1) IN GENERAL.—Section 505 of the Federal
21 Food, Drug, and Cosmetic Act (21 U.S.C. 355) (as
22 amended by section 210(a)(2)(B)(ii)) is amended in
23 subsection (c) by striking paragraph (2) and insert-
24 ing the following:

25 “(2) PATENT INFORMATION.—

1 “(A) IN GENERAL.—Not later than the
2 date that is 30 days after the date of an order
3 approving an application under subsection (b)
4 (unless the Secretary extends the date because
5 of extraordinary or unusual circumstances), the
6 holder of the application shall file with the Sec-
7 retary the patent information described in sub-
8 paragraph (C) with respect to any patent—

9 “(i)(I) that claims the drug for which
10 the application was approved; or

11 “(II) that claims an approved method
12 of using the drug; and

13 “(ii) with respect to which a claim of
14 patent infringement could reasonably be
15 asserted if a person not licensed by the
16 owner engaged in the manufacture, use, or
17 sale of the drug.

18 “(B) SUBSEQUENTLY ISSUED PATENTS.—
19 In a case in which a patent described in sub-
20 paragraph (A) is issued after the date of an
21 order approving an application under subsection
22 (b), the holder of the application shall file with
23 the Secretary the patent information described
24 in subparagraph (C) not later than the date
25 that is 30 days after the date on which the pat-

ent is issued (unless the Secretary extends the date because of extraordinary or unusual circumstances).

“(C) PATENT INFORMATION.—The patent information required to be filed under subparagraph (A) or (B) includes—

“(i) the patent number;

“(ii) the expiration date of the patent;

“(iii) with respect to each claim of the patent—

“(I) whether the patent claims the drug or claims a method of using the drug; and

“(II) whether the claim covers—

“(aa) a drug substance;

“(bb) a drug formulation;

“(cc) a drug composition; or

“(dd) a method of use;

“(iv) if the patent claims a method of use, the approved use covered by the claim;

“(v) the identity of the owner of the patent (including the identity of any agent of the patent owner); and

“(vi) a declaration that the applicant, as of the date of the filing, has provided

1 complete and accurate patent information
2 for all patents described in subparagraph
3 (A).

4 “(D) PUBLICATION.—On filing of patent
5 information required under subparagraph (A)
6 or (B), the Secretary shall—

7 “(i) immediately publish the informa-
8 tion described in clauses (i) through (iv) of
9 subparagraph (C); and

10 “(ii) make the information described
11 in clauses (v) and (vi) of subparagraph (C)
12 available to the public on request.

13 “(E) CIVIL ACTION FOR CORRECTION OR
14 DELETION OF PATENT INFORMATION.—

15 “(i) IN GENERAL.—A person that has
16 filed an application under subsection (b)(2)
17 or (j) for a drug may bring a civil action
18 against the holder of the approved applica-
19 tion for the drug seeking an order requir-
20 ing that the holder of the application
21 amend the application—

22 “(I) to correct patent information
23 filed under subparagraph (A); or

1 “(II) to delete the patent infor-
2 mation in its entirety for the reason
3 that—

4 “(aa) the patent does not
5 claim the drug for which the ap-
6 plication was approved; or

7 “(bb) the patent does not
8 claim an approved method of
9 using the drug.

10 “(ii) LIMITATIONS.—Clause (i) does
11 not authorize—

12 “(I) a civil action to correct pat-
13 ent information filed under subpara-
14 graph (B); or

15 “(II) an award of damages in a
16 civil action under clause (i).

17 “(F) NO CLAIM FOR PATENT INFRINGE-
18 MENT.—An owner of a patent with respect to
19 which a holder of an application fails to file in-
20 formation on or before the date required under
21 subparagraph (A) or (B) shall be barred from
22 bringing a civil action for infringement of the
23 patent against a person that—

24 “(i) has filed an application under
25 subsection (b)(2) or (j); or

1 “(ii) manufactures, uses, offers to sell,
2 or sells a drug approved under an applica-
3 tion under subsection (b)(2) or (j).”.

4 (2) TRANSITION PROVISION.—

5 (A) FILING OF PATENT INFORMATION.—

6 Each holder of an application for approval of a
7 new drug under section 505(b) of the Federal
8 Food, Drug, and Cosmetic Act (21 U.S.C.
9 355(b)) that has been approved before the date
10 of enactment of this Act shall amend the appli-
11 cation to include the patent information re-
12 quired under the amendment made by para-
13 graph (1) not later than the date that is 30
14 days after the date of enactment of this Act
15 (unless the Secretary of Health and Human
16 Services extends the date because of extraor-
17 dinary or unusual circumstances).

18 (B) NO CLAIM FOR PATENT INFRINGE-
19 MENT.—An owner of a patent with respect to
20 which a holder of an application under sub-
21 section (b) of section 505 of the Federal Food,
22 Drug, and Cosmetic Act (21 U.S.C. 355) fails
23 to file information on or before the date re-
24 quired under subparagraph (A) shall be barred

from bringing a civil action for infringement of
the patent against a person that—

(i) has filed an application under sub-
section (b)(2) or (j) of that section; or

(ii) manufactures, uses, offers to sell,
or sells a drug approved under an applica-
tion under subsection (b)(2) or (j) of that
section.

(b) FILING WITH AN APPLICATION.—Section 505 of
the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
355) is amended—

(1) in subsection (b)(2)—

(A) in subparagraph (A), by striking
“and” at the end;

(B) in subparagraph (B), by striking the
period at the end and inserting “; and”; and

(C) by adding at the end the following:

“(C) with respect to a patent that claims
both the drug and a method of using the drug
or claims more than 1 method of using the drug
for which the application is filed—

“(i) a certification under subpara-
graph (A)(iv) on a claim-by-claim basis;
and

1 “(ii) a statement under subparagraph
 2 (B) regarding the method of use claim.”;
 3 and

4 (2) in subsection (j)(2)(A), by inserting after
 5 clause (viii) the following:

6 “With respect to a patent that claims both the drug and
 7 a method of using the drug or claims more than 1 method
 8 of using the drug for which the application is filed, the
 9 application shall contain a certification under clause
 10 (vii)(IV) on a claim-by-claim basis and a statement under
 11 clause (viii) regarding the method of use claim.”.

12 **SEC. 202. LIMITATION OF 30-MONTH STAY TO CERTAIN PAT-**
 13 **ENTS.**

14 (a) ABBREVIATED NEW DRUG APPLICATIONS.—Sec-
 15 tion 505(j)(5) of the Federal Food, Drug, and Cosmetic
 16 Act (21 U.S.C. 355(j)(5)) is amended—

17 (1) in subparagraph (B)—

18 (A) in clause (iii)—

19 (i) by striking “(iii) If the applicant
 20 made a certification described in subclause
 21 (IV) of paragraph (2)(A)(vii),” and insert-
 22 ing the following:

23 “(iii) SUBCLAUSE (IV) CERTIFICATION
 24 WITH RESPECT TO CERTAIN PATENTS.—If
 25 the applicant made a certification de-

scribed in paragraph (2)(A)(vii)(IV) with respect to a patent (other than a patent that claims a process for manufacturing the listed drug) for which patent information was filed with the Secretary under subsection (c)(2)(A),”;

(ii) by adding at the end the following: “The 30-month period provided under the second sentence of this clause shall not apply to a certification under paragraph (2)(A)(vii)(IV) made with respect to a patent for which patent information was filed with the Secretary under subsection (c)(2)(B).”;

(B) by redesignating clause (iv) as clause (v); and

(C) by inserting after clause (iii) the following:

“(iv) SUBCLAUSE (IV) CERTIFICATION WITH RESPECT TO OTHER PATENTS.—

“(I) IN GENERAL.—If the applicant made a certification described in paragraph (2)(A)(vii)(IV) with respect to a patent not described in clause (iii) for which patent information was

1 published by the Secretary under sub-
2 section (c)(2)(D), the approval shall
3 be made effective on the date that is
4 45 days after the date on which the
5 notice provided under paragraph
6 (2)(B) was received, unless a civil ac-
7 tion for infringement of the patent,
8 accompanied by a motion for prelimi-
9 nary injunction to enjoin the applicant
10 from engaging in the commercial
11 manufacture or sale of the drug, was
12 filed on or before the date that is 45
13 days after the date on which the no-
14 tice was received, in which case the
15 approval shall be made effective—

16 “(aa) on the date of a court
17 action declining to grant a pre-
18 liminary injunction; or

19 “(bb) if the court has grant-
20 ed a preliminary injunction pro-
21 hibiting the applicant from en-
22 gaging in the commercial manu-
23 facture or sale of the drug—

24 “(AA) on issuance by a
25 court of a determination

1 that the patent is invalid or
2 is not infringed;

3 “(BB) on issuance by a
4 court of an order revoking
5 the preliminary injunction or
6 permitting the applicant to
7 engage in the commercial
8 manufacture or sale of the
9 drug; or

10 “(CC) on the date spec-
11 ified in a court order under
12 section 271(e)(4)(A) of title
13 35, United States Code, if
14 the court determines that
15 the patent is infringed.

16 “(II) COOPERATION.—Each of
17 the parties shall reasonably cooperate
18 in expediting a civil action under sub-
19 clause (I).

20 “(III) EXPEDITED NOTIFICA-
21 TION.—If the notice under paragraph
22 (2)(B) contains an address for the re-
23 ceipt of expedited notification of a
24 civil action under subclause (I), the
25 plaintiff shall, on the date on which

1 the complaint is filed, simultaneously
2 cause a notification of the civil action
3 to be delivered to that address by the
4 next business day.”; and

5 (2) by inserting after subparagraph (B) the fol-
6 lowing:

7 “(C) FAILURE TO BRING INFRINGEMENT
8 ACTION.—If, in connection with an application
9 under this subsection, the applicant provides an
10 owner of a patent notice under paragraph
11 (2)(B) with respect to the patent, and the
12 owner of the patent fails to bring a civil action
13 against the applicant for infringement of the
14 patent on or before the date that is 45 days
15 after the date on which the notice is received,
16 the owner of the patent shall be barred from
17 bringing a civil action for infringement of the
18 patent in connection with the development,
19 manufacture, use, offer to sell, or sale of the
20 drug for which the application was filed or ap-
21 proved under this subsection.”.

22 (b) OTHER APPLICATIONS.—Section 505(c) of the
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(c))
24 (as amended by section 210(a)(3)(A)(iii)) is amended—

25 (1) in paragraph (3)—

1 (A) in subparagraph (C)—

2 (i) by striking “(C) If the applicant
3 made a certification described in clause
4 (iv) of subsection (b)(2)(A),” and inserting
5 the following:

6 “(C) CLAUSE (iv) CERTIFICATION WITH
7 RESPECT TO CERTAIN PATENTS.—If the appli-
8 cant made a certification described in sub-
9 section (b)(2)(A)(iv) with respect to a patent
10 (other than a patent that claims a process for
11 manufacturing the listed drug) for which patent
12 information was filed with the Secretary under
13 paragraph (2)(A),”; and

14 (ii) by adding at the end the fol-
15 lowing: “The 30-month period provided
16 under the second sentence of this subpara-
17 graph shall not apply to a certification
18 under subsection (b)(2)(A)(iv) made with
19 respect to a patent for which patent infor-
20 mation was filed with the Secretary under
21 paragraph (2)(B).”; and

22 (B) by inserting after subparagraph (C)
23 the following:

24 “(D) CLAUSE (iv) CERTIFICATION WITH
25 RESPECT TO OTHER PATENTS.—

1 “(i) IN GENERAL.—If the applicant
2 made a certification described in sub-
3 section (b)(2)(A)(iv) with respect to a pat-
4 ent not described in subparagraph (C) for
5 which patent information was published by
6 the Secretary under paragraph (2)(D), the
7 approval shall be made effective on the
8 date that is 45 days after the date on
9 which the notice provided under subsection
10 (b)(3) was received, unless a civil action
11 for infringement of the patent, accom-
12 panied by a motion for preliminary injunc-
13 tion to enjoin the applicant from engaging
14 in the commercial manufacture or sale of
15 the drug, was filed on or before the date
16 that is 45 days after the date on which the
17 notice was received, in which case the ap-
18 proval shall be made effective—

19 “(I) on the date of a court action
20 declining to grant a preliminary in-
21 junction; or

22 “(II) if the court has granted a
23 preliminary injunction prohibiting the
24 applicant from engaging in the com-

1 mercian manufacture or sale of the
2 drug—

3 “(aa) on issuance by a court
4 of a determination that the pat-
5 ent is invalid or is not infringed;

6 “(bb) on issuance by a court
7 of an order revoking the prelimi-
8 nary injunction or permitting the
9 applicant to engage in the com-
10 mercial manufacture or sale of
11 the drug; or

12 “(cc) on the date specified
13 in a court order under section
14 271(e)(4)(A) of title 35, United
15 States Code, if the court deter-
16 mines that the patent is in-
17 fringed.

18 “(ii) COOPERATION.—Each of the
19 parties shall reasonably cooperate in expe-
20 diting a civil action under clause (i).

21 “(iii) EXPEDITED NOTIFICATION.—If
22 the notice under subsection (b)(3) contains
23 an address for the receipt of expedited no-
24 tification of a civil action under clause (i),
25 the plaintiff shall, on the date on which the

1 complaint is filed, simultaneously cause a
 2 notification of the civil action to be deliv-
 3 ered to that address by the next business
 4 day.”; and

5 (2) by inserting after paragraph (3) the fol-
 6 lowing:

7 “(4) FAILURE TO BRING INFRINGEMENT AC-
 8 TION.—If, in connection with an application under
 9 subsection (b)(2), the applicant provides an owner of
 10 a patent notice under subsection (b)(3) with respect
 11 to the patent, and the owner of the patent fails to
 12 bring a civil action against the applicant for in-
 13 fringement of the patent on or before the date that
 14 is 45 days after the date on which the notice is re-
 15 ceived, the owner of the patent shall be barred from
 16 bringing a civil action for infringement of the patent
 17 in connection with the development, manufacture,
 18 use, offer to sell, or sale of the drug for which the
 19 application was filed or approved under subsection
 20 (b)(2).”.

21 (c) EFFECTIVE DATE.—

22 (1) IN GENERAL.—The amendments made by
 23 subsections (a) and (b) shall be effective with re-
 24 spect to any certification under subsection
 25 (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of

1 the Federal Food, Drug, and Cosmetic Act (21
2 U.S.C. 355) made after the date of enactment of
3 this Act in an application filed under subsection
4 (b)(2) or (j) of that section.

5 (2) TRANSITION PROVISION.—In the case of ap-
6 plications under section 505(b) of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 355(b)) filed be-
8 fore the date of enactment of this Act—

9 (A) a patent (other than a patent that
10 claims a process for manufacturing a listed
11 drug) for which information was submitted to
12 the Secretary of Health and Human Services
13 under section 505(b)(1) of the Federal Food,
14 Drug, and Cosmetic Act (as in effect on the day
15 before the date of enactment of this Act) shall
16 be subject to subsections (c)(3)(C) and
17 (j)(5)(B)(iii) of section 505 of the Federal
18 Food, Drug, and Cosmetic Act (as amended by
19 this section); and

20 (B) any other patent (including a patent
21 for which information was submitted to the
22 Secretary under section 505(c)(2) of that Act
23 (as in effect on the day before the date of en-
24 actment of this Act)) shall be subject to sub-
25 sections (c)(3)(D) and (j)(5)(B)(iv) of section

1 505 of the Federal Food, Drug, and Cosmetic
2 Act (as amended by this section).

3 **SEC. 203. EXCLUSIVITY FOR ACCELERATED GENERIC DRUG**
4 **APPLICANTS.**

5 (a) IN GENERAL.—Section 505(j)(5) of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as
7 amended by section 202(a)) is amended—

8 (1) in subparagraph (B)(v), by striking sub-
9 clause (II) and inserting the following:

10 “(II) the earlier of—

11 “(aa) the date of a final de-
12 cision of a court (from which no
13 appeal has been or can be taken,
14 other than a petition to the Su-
15 preme Court for a writ of certio-
16 rari) holding that the patent that
17 is the subject of the certification
18 is invalid or not infringed; or

19 “(bb) the date of a settle-
20 ment order or consent decree
21 signed by a Federal judge that
22 enters a final judgment and in-
23 cludes a finding that the patent
24 that is the subject of the certifi-

1 cation is invalid or not in-
2 fringed;”; and

3 (2) by inserting after subparagraph (C) the fol-
4 lowing:

5 “(D) FORFEITURE OF 180-DAY PERIOD.—

6 “(i) DEFINITIONS.—In this subpara-
7 graph:

8 “(I) APPLICATION.—The term
9 ‘application’ means an application for
10 approval of a drug under this sub-
11 section containing a certification
12 under paragraph (2)(A)(vii)(IV) with
13 respect to a patent.

14 “(II) FIRST APPLICATION.—The
15 term ‘first application’ means the first
16 application to be filed for approval of
17 the drug.

18 “(III) FORFEITURE EVENT.—
19 The term ‘forfeiture event’, with re-
20 spect to an application under this sub-
21 section, means the occurrence of any
22 of the following:

23 “(aa) FAILURE TO MAR-
24 KET.—The applicant fails to
25 market the drug by the later of—

1 “(AA) the date that is
2 60 days after the date on
3 which the approval of the
4 application for the drug is
5 made effective under clause
6 (iii) or (iv) of subparagraph
7 (B) (unless the Secretary ex-
8 tends the date because of ex-
9 traordinary or unusual cir-
10 cumstances); or

11 “(BB) if 1 or more civil
12 actions have been brought
13 against the applicant for in-
14 fringement of a patent sub-
15 ject to a certification under
16 paragraph (2)(A)(vii)(IV) or
17 1 or more civil actions have
18 been brought by the appli-
19 cant for a declaratory judg-
20 ment that such a patent is
21 invalid or not infringed, the
22 date that is 60 days after
23 the date of a final decision
24 (from which no appeal has
25 been or can be taken, other

1 than a petition to the Su-
2 preme Court for a writ of
3 certiorari) in the last of
4 those civil actions to be de-
5 cided (unless the Secretary
6 extends the date because of
7 extraordinary or unusual
8 circumstances).

9 “(bb) WITHDRAWAL OF AP-
10 PLICATION.—The applicant with-
11 draws the application.

12 “(cc) AMENDMENT OF CER-
13 TIFICATION.—The applicant, vol-
14 untarily or as a result of a settle-
15 ment or defeat in patent litiga-
16 tion, amends the certification
17 from a certification under para-
18 graph (2)(A)(vii)(IV) to a certifi-
19 cation under paragraph
20 (2)(A)(vii)(III).

21 “(dd) FAILURE TO OBTAIN
22 APPROVAL.—The applicant fails
23 to obtain tentative approval of an
24 application within 30 months
25 after the date on which the appli-

1 cation is filed, unless the failure
2 is caused by—

3 “(AA) a change in the
4 requirements for approval of
5 the application imposed
6 after the date on which the
7 application is filed; or

8 “(BB) other extraor-
9 dinary circumstances war-
10 ranting an exception, as de-
11 termined by the Secretary.

12 “(ee) FAILURE TO CHAL-
13 LENGE PATENT.—In a case in
14 which, after the date on which
15 the applicant submitted the ap-
16 plication, new patent information
17 is submitted under subsection
18 (c)(2) for the listed drug for a
19 patent for which certification is
20 required under paragraph (2)(A),
21 the applicant fails to submit, not
22 later than the date that is 60
23 days after the date on which the
24 Secretary publishes the new pat-
25 ent information under paragraph

1 (7)(A)(iii) (unless the Secretary
2 extends the date because of ex-
3 traordinary or unusual cir-
4 cumstances)—

5 “(AA) a certification
6 described in paragraph
7 (2)(A)(vii)(IV) with respect
8 to the patent to which the
9 new patent information re-
10 lates; or

11 “(BB) a statement that
12 any method of use claim of
13 that patent does not claim a
14 use for which the applicant
15 is seeking approval under
16 this subsection in accord-
17 ance with paragraph
18 (2)(A)(viii).

19 “(ff) UNLAWFUL CON-
20 DUCT.—The Federal Trade Com-
21 mission determines that the ap-
22 plicant engaged in unlawful con-
23 duct with respect to the applica-
24 tion in violation of section 1 of
25 the Sherman Act (15 U.S.C. 1).

1 “(IV) SUBSEQUENT APPLICA-
 2 TION.—The term ‘subsequent applica-
 3 tion’ means an application for ap-
 4 proval of a drug that is filed subse-
 5 quent to the filing of a first applica-
 6 tion for approval of that drug.

7 “(ii) FORFEITURE OF 180-DAY PE-
 8 RIOD.—

9 “(I) IN GENERAL.—Except as
 10 provided in subclause (II), if a for-
 11 feiture event occurs with respect to a
 12 first application—

13 “(aa) the 180-day period
 14 under subparagraph (B)(v) shall
 15 be forfeited by the first applicant;
 16 and

17 “(bb) any subsequent appli-
 18 cation shall become effective as
 19 provided under clause (i), (ii),
 20 (iii), or (iv) of subparagraph (B),
 21 and clause (v) of subparagraph
 22 (B) shall not apply to the subse-
 23 quent application.

24 “(II) FORFEITURE TO FIRST
 25 SUBSEQUENT APPLICANT.—If the sub-

1 sequent application that is the first to
2 be made effective under subclause (I)
3 was the first among a number of sub-
4 sequent applications to be filed—

5 “(aa) that first subsequent
6 application shall be treated as
7 the first application under this
8 subparagraph (including sub-
9 clause (I)) and as the previous
10 application under subparagraph
11 (B)(v); and

12 “(bb) any other subsequent
13 applications shall become effec-
14 tive as provided under clause (i),
15 (ii), (iii), or (iv) of subparagraph
16 (B), but clause (v) of subpara-
17 graph (B) shall apply to any such
18 subsequent application.

19 “(iii) AVAILABILITY.—The 180-day
20 period under subparagraph (B)(v) shall be
21 available to a first applicant submitting an
22 application for a drug with respect to any
23 patent without regard to whether an appli-
24 cation has been submitted for the drug
25 under this subsection containing such a

1 certification with respect to a different pat-
 2 ent.

3 “(iv) APPLICABILITY.—The 180-day
 4 period described in subparagraph (B)(v)
 5 shall apply to an application only if a civil
 6 action is brought against the applicant for
 7 infringement of a patent that is the subject
 8 of the certification.”.

9 (b) APPLICABILITY.—The amendment made by sub-
 10 section (a) shall be effective only with respect to an appli-
 11 cation filed under section 505(j) of the Federal Food,
 12 Drug, and Cosmetic Act (21 U.S.C. 355(j)) after the date
 13 of enactment of this Act for a listed drug for which no
 14 certification under section 505(j)(2)(A)(vii)(IV) of that
 15 Act was made before the date of enactment of this Act,
 16 except that if a forfeiture event described in section
 17 505(j)(5)(D)(i)(III)(ff) of that Act occurs in the case of
 18 an applicant, the applicant shall forfeit the 180-day period
 19 under section 505(j)(5)(B)(v) of that Act without regard
 20 to when the applicant made a certification under section
 21 505(j)(2)(A)(vii)(IV) of that Act.

22 **SEC. 204. FAIR TREATMENT FOR INNOVATORS.**

23 (a) BASIS FOR APPLICATION.—Section 505 of the
 24 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355)
 25 is amended—

1 (1) in subsection (b)(3)(B), by striking the sec-
2 ond sentence and inserting “The notice shall include
3 a detailed statement of the factual and legal basis of
4 the applicant’s opinion that, as of the date of the no-
5 tice, the patent is not valid or is not infringed, and
6 shall include, as appropriate for the relevant patent,
7 a description of the applicant’s proposed drug sub-
8 stance, drug formulation, drug composition, or meth-
9 od of use. All information disclosed under this sub-
10 paragraph shall be treated as confidential and may
11 be used only for purposes relating to patent adju-
12 dication. Nothing in this subparagraph precludes the
13 applicant from amending the factual or legal basis
14 on which the applicant relies in patent litigation.”;
15 and

16 (2) in subsection (j)(2)(B)(ii), by striking the
17 second sentence and inserting “The notice shall in-
18 clude a detailed statement of the factual and legal
19 basis of the opinion of the applicant that, as of the
20 date of the notice, the patent is not valid or is not
21 infringed, and shall include, as appropriate for the
22 relevant patent, a description of the applicant’s pro-
23 posed drug substance, drug formulation, drug com-
24 position, or method of use. All information disclosed
25 under this subparagraph shall be treated as con-

1 fidential and may be used only for purposes relating
 2 to patent adjudication. Nothing in this subparagraph
 3 precludes the applicant from amending the factual
 4 or legal basis on which the applicant relies in patent
 5 litigation.”.

6 (b) INJUNCTIVE RELIEF.—Section 505(j)(5)(B) of
 7 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
 8 355(j)(5)(B)) (as amended by section 202(a)(1)) is
 9 amended—

10 (1) in clause (iii), by adding at the end the fol-
 11 lowing: “A court shall not regard the extent of the
 12 ability of an applicant to pay monetary damages as
 13 a whole or partial basis on which to deny a prelimi-
 14 nary or permanent injunction under this clause.”;
 15 and

16 (2) in clause (iv), by adding at the end the fol-
 17 lowing:

18 “(IV) INJUNCTIVE RELIEF.—A court shall
 19 not regard the extent of the ability of an appli-
 20 cant to pay monetary damages as a whole or
 21 partial basis on which to deny a preliminary or
 22 permanent injunction under this clause.”.

23 **SEC. 205. BIOEQUIVALENCE.**

24 (a) IN GENERAL.—The amendments to part 320 of
 25 title 21, Code of Federal Regulations, promulgated by the

1 Commissioner of Food and Drugs on July 17, 1991 (57
 2 Fed. Reg. 17997 (April 28, 1992)), shall continue in effect
 3 as an exercise of authorities under sections 501, 502, 505,
 4 and 701 of the Federal Food, Drug, and Cosmetic Act
 5 (21 U.S.C. 351, 352, 355, 371).

6 (b) EFFECT.—Subsection (a) does not affect the au-
 7 thority of the Commissioner of Food and Drugs to amend
 8 part 320 of title 21, Code of Federal Regulations.

9 (c) EFFECT OF SECTION.—This section shall not be
 10 construed to alter the authority of the Secretary of Health
 11 and Human Services to regulate biological products under
 12 the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301
 13 et seq.). Any such authority shall be exercised under that
 14 Act as in effect on the day before the date of enactment
 15 of this Act.

16 **SEC. 206. CLARIFICATION OF STATE AUTHORITY RELATING**
 17 **TO MEDICAID DRUG REBATE AGREEMENTS.**

18 Section 1927 of the Social Security Act (42 U.S.C.
 19 1396r–8) is amended by adding at the end the following:

20 “(l) RULE OF CONSTRUCTION.—Nothing in this sec-
 21 tion shall be construed as prohibiting a State from—

22 “(1) directly entering into rebate agreements
 23 (on the State’s own initiative or under a section
 24 1115 waiver approved by the Secretary before, on,
 25 or after the date of enactment of this subsection)

1 that are similar to a rebate agreement described in
 2 subsection (b) with a manufacturer for purposes of
 3 ensuring the affordability of outpatient prescription
 4 drugs in order to provide access to such drugs by
 5 residents of a State who are not otherwise eligible
 6 for medical assistance under this title; or

7 “(2) making prior authorization (that satisfies
 8 the requirements of subsection (d) and that does not
 9 violate any requirements of this title that are de-
 10 signed to ensure access to medically necessary pre-
 11 scribed drugs for individuals enrolled in the State
 12 program under this title) a condition of not partici-
 13 pating in such a similar rebate agreement.”.

14 **SEC. 207. IMPORTATION OF PRESCRIPTION DRUGS.**

15 (a) IN GENERAL.—Chapter VIII of the Federal
 16 Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.)
 17 is amended by striking section 804 and inserting the fol-
 18 lowing:

19 **“SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.**

20 “(a) DEFINITIONS.—In this section:

21 “(1) IMPORTER.—The term ‘importer’ means a
 22 pharmacist or wholesaler.

23 “(2) PHARMACIST.—The term ‘pharmacist’
 24 means a person licensed by a State to practice phar-

1 macy, including the dispensing and selling of pre-
2 scription drugs.

3 “(3) PRESCRIPTION DRUG.—The term ‘pre-
4 scription drug’ means a drug subject to section
5 503(b), other than—

6 “(A) a controlled substance (as defined in
7 section 102 of the Controlled Substances Act
8 (21 U.S.C. 802));

9 “(B) a biological product (as defined in
10 section 351 of the Public Health Service Act
11 (42 U.S.C. 262));

12 “(C) an infused drug (including a peri-
13 toneal dialysis solution);

14 “(D) an intravenously injected drug; or

15 “(E) a drug that is inhaled during surgery.

16 “(4) QUALIFYING LABORATORY.—The term
17 ‘qualifying laboratory’ means a laboratory in the
18 United States that has been approved by the Sec-
19 retary for the purposes of this section.

20 “(5) WHOLESALER.—

21 “(A) IN GENERAL.—The term ‘wholesaler’
22 means a person licensed as a wholesaler or dis-
23 tributor of prescription drugs in the United
24 States under section 503(e)(2)(A).

1 “(B) EXCLUSION.—The term ‘wholesaler’
2 does not include a person authorized to import
3 drugs under section 801(d)(1).

4 “(b) REGULATIONS.—The Secretary, after consulta-
5 tion with the United States Trade Representative and the
6 Commissioner of Customs, shall promulgate regulations
7 permitting pharmacists and wholesalers to import pre-
8 scription drugs from Canada into the United States.

9 “(c) LIMITATION.—The regulations under subsection
10 (b) shall—

11 “(1) require that safeguards be in place to en-
12 sure that each prescription drug imported under the
13 regulations complies with section 505 (including
14 with respect to being safe and effective for the in-
15 tended use of the prescription drug), with sections
16 501 and 502, and with other applicable require-
17 ments of this Act;

18 “(2) require that an importer of a prescription
19 drug under the regulations comply with subsections
20 (d)(1) and (e); and

21 “(3) contain any additional provisions deter-
22 mined by the Secretary to be appropriate as a safe-
23 guard to protect the public health or as a means to
24 facilitate the importation of prescription drugs.

25 “(d) INFORMATION AND RECORDS.—

1 “(1) IN GENERAL.—The regulations under sub-
2 section (b) shall require an importer of a prescrip-
3 tion drug under subsection (b) to submit to the Sec-
4 retary the following information and documentation:

5 “(A) The name and quantity of the active
6 ingredient of the prescription drug.

7 “(B) A description of the dosage form of
8 the prescription drug.

9 “(C) The date on which the prescription
10 drug is shipped.

11 “(D) The quantity of the prescription drug
12 that is shipped.

13 “(E) The point of origin and destination of
14 the prescription drug.

15 “(F) The price paid by the importer for
16 the prescription drug.

17 “(G) Documentation from the foreign sell-
18 er specifying—

19 “(i) the original source of the pre-
20 scription drug; and

21 “(ii) the quantity of each lot of the
22 prescription drug originally received by the
23 seller from that source.

1 “(H) The lot or control number assigned
2 to the prescription drug by the manufacturer of
3 the prescription drug.

4 “(I) The name, address, telephone number,
5 and professional license number (if any) of the
6 importer.

7 “(J)(i) In the case of a prescription drug
8 that is shipped directly from the first foreign
9 recipient of the prescription drug from the
10 manufacturer:

11 “(I) Documentation demonstrating
12 that the prescription drug was received by
13 the recipient from the manufacturer and
14 subsequently shipped by the first foreign
15 recipient to the importer.

16 “(II) Documentation of the quantity
17 of each lot of the prescription drug re-
18 ceived by the first foreign recipient dem-
19 onstrating that the quantity being im-
20 ported into the United States is not more
21 than the quantity that was received by the
22 first foreign recipient.

23 “(III)(aa) In the case of an initial im-
24 ported shipment, documentation dem-
25 onstrating that each batch of the prescrip-

1 tion drug in the shipment was statistically
2 sampled and tested for authenticity and
3 degradation.

4 “(bb) In the case of any subsequent
5 shipment, documentation demonstrating
6 that a statistically valid sample of the ship-
7 ment was tested for authenticity and deg-
8 radation.

9 “(ii) In the case of a prescription drug
10 that is not shipped directly from the first for-
11 eign recipient of the prescription drug from the
12 manufacturer, documentation demonstrating
13 that each batch in each shipment offered for
14 importation into the United States was statis-
15 tically sampled and tested for authenticity and
16 degradation.

17 “(K) Certification from the importer or
18 manufacturer of the prescription drug that the
19 prescription drug—

20 “(i) is approved for marketing in the
21 United States; and

22 “(ii) meets all labeling requirements
23 under this Act.

24 “(L) Laboratory records, including com-
25 plete data derived from all tests necessary to

1 ensure that the prescription drug is in compli-
 2 ance with established specifications and stand-
 3 ards.

4 “(M) Documentation demonstrating that
 5 the testing required by subparagraphs (J) and
 6 (L) was conducted at a qualifying laboratory.

7 “(N) Any other information that the Sec-
 8 retary determines is necessary to ensure the
 9 protection of the public health.

10 “(2) MAINTENANCE BY THE SECRETARY.—The
 11 Secretary shall maintain information and docu-
 12 mentation submitted under paragraph (1) for such
 13 period of time as the Secretary determines to be nec-
 14 essary.

15 “(e) TESTING.—The regulations under subsection (b)
 16 shall require—

17 “(1) that testing described in subparagraphs
 18 (J) and (L) of subsection (d)(1) be conducted by the
 19 importer or by the manufacturer of the prescription
 20 drug at a qualified laboratory;

21 “(2) if the tests are conducted by the im-
 22 porter—

23 “(A) that information needed to—

24 “(i) authenticate the prescription drug
 25 being tested; and

1 “(ii) confirm that the labeling of the
2 prescription drug complies with labeling re-
3 quirements under this Act;
4 be supplied by the manufacturer of the pre-
5 scription drug to the pharmacist or wholesaler;
6 and

7 “(B) that the information supplied under
8 subparagraph (A) be kept in strict confidence
9 and used only for purposes of testing or other-
10 wise complying with this Act; and

11 “(3) may include such additional provisions as
12 the Secretary determines to be appropriate to pro-
13 vide for the protection of trade secrets and commer-
14 cial or financial information that is privileged or
15 confidential.

16 “(f) REGISTRATION OF FOREIGN SELLERS.—Any es-
17 tablishment within Canada engaged in the distribution of
18 a prescription drug that is imported or offered for impor-
19 tation into the United States shall register with the Sec-
20 retary the name and place of business of the establish-
21 ment.

22 “(g) SUSPENSION OF IMPORTATION.—The Secretary
23 shall require that importations of a specific prescription
24 drug or importations by a specific importer under sub-
25 section (b) be immediately suspended on discovery of a

1 pattern of importation of the prescription drugs or by the
2 importer that is counterfeit or in violation of any require-
3 ment under this section, until an investigation is com-
4 pleted and the Secretary determines that the public is ade-
5 quately protected from counterfeit and violative prescrip-
6 tion drugs being imported under subsection (b).

7 “(h) APPROVED LABELING.—The manufacturer of a
8 prescription drug shall provide an importer written au-
9 thorization for the importer to use, at no cost, the ap-
10 proved labeling for the prescription drug.

11 “(i) PROHIBITION OF DISCRIMINATION.—

12 “(1) IN GENERAL.—It shall be unlawful for a
13 manufacturer of a prescription drug to discriminate
14 against, or cause any other person to discriminate
15 against, a pharmacist or wholesaler that purchases
16 or offers to purchase a prescription drug from the
17 manufacturer or from any person that distributes a
18 prescription drug manufactured by the drug manu-
19 facturer.

20 “(2) DISCRIMINATION.—For the purposes of
21 paragraph (1), a manufacturer of a prescription
22 drug shall be considered to discriminate against a
23 pharmacist or wholesaler if the manufacturer enters
24 into a contract for sale of a prescription drug, places

1 a limit on supply, or employs any other measure,
2 that has the effect of—

3 “(A) providing pharmacists or wholesalers
4 access to prescription drugs on terms or condi-
5 tions that are less favorable than the terms or
6 conditions provided to a foreign purchaser
7 (other than a charitable or humanitarian orga-
8 nization) of the prescription drug; or

9 “(B) restricting the access of pharmacists
10 or wholesalers to a prescription drug that is
11 permitted to be imported into the United States
12 under this section.

13 “(j) CHARITABLE CONTRIBUTIONS.—Notwith-
14 standing any other provision of this section, section
15 801(d)(1) continues to apply to a prescription drug that
16 is donated or otherwise supplied at no charge by the man-
17 ufacturer of the drug to a charitable or humanitarian or-
18 ganization (including the United Nations and affiliates)
19 or to a government of a foreign country.

20 “(k) WAIVER AUTHORITY FOR IMPORTATION BY IN-
21 DIVIDUALS.—

22 “(1) DECLARATIONS.—Congress declares that
23 in the enforcement against individuals of the prohi-
24 bition of importation of prescription drugs and de-
25 vices, the Secretary should—

1 “(A) focus enforcement on cases in which
2 the importation by an individual poses a signifi-
3 cant threat to public health; and

4 “(B) exercise discretion to permit individ-
5 uals to make such importations in cir-
6 cumstances in which—

7 “(i) the importation is clearly for per-
8 sonal use; and

9 “(ii) the prescription drug or device
10 imported does not appear to present an
11 unreasonable risk to the individual.

12 “(2) WAIVER AUTHORITY.—

13 “(A) IN GENERAL.—The Secretary may
14 grant to individuals, by regulation or on a case-
15 by-case basis, a waiver of the prohibition of im-
16 portation of a prescription drug or device or
17 class of prescription drugs or devices, under
18 such conditions as the Secretary determines to
19 be appropriate.

20 “(B) GUIDANCE ON CASE-BY-CASE WAIV-
21 ERS.—The Secretary shall publish, and update
22 as necessary, guidance that accurately describes
23 circumstances in which the Secretary will con-
24 sistently grant waivers on a case-by-case basis
25 under subparagraph (A), so that individuals

1 may know with the greatest practicable degree
2 of certainty whether a particular importation
3 for personal use will be permitted.

4 “(3) DRUGS IMPORTED FROM CANADA.—In
5 particular, the Secretary shall by regulation grant
6 individuals a waiver to permit individuals to import
7 into the United States a prescription drug that—

8 “(A) is imported from a licensed pharmacy
9 for personal use by an individual, not for resale,
10 in quantities that do not exceed a 90-day sup-
11 ply;

12 “(B) is accompanied by a copy of a valid
13 prescription;

14 “(C) is imported from Canada, from a sell-
15 er registered with the Secretary;

16 “(D) is a prescription drug approved by
17 the Secretary under chapter V;

18 “(E) is in the form of a final finished dos-
19 age that was manufactured in an establishment
20 registered under section 510; and

21 “(F) is imported under such other condi-
22 tions as the Secretary determines to be nec-
23 essary to ensure public safety.

24 “(l) STUDIES; REPORTS.—

1 “(1) BY THE INSTITUTE OF MEDICINE OF THE
2 NATIONAL ACADEMY OF SCIENCES.—

3 “(A) STUDY.—

4 “(i) IN GENERAL.—The Secretary
5 shall request that the Institute of Medicine
6 of the National Academy of Sciences con-
7 duct a study of—

8 “(I) importations of prescription
9 drugs made under the regulations
10 under subsection (b); and

11 “(II) information and docu-
12 mentation submitted under subsection
13 (d).

14 “(ii) REQUIREMENTS.—In conducting
15 the study, the Institute of Medicine shall—

16 “(I) evaluate the compliance of
17 importers with the regulations under
18 subsection (b);

19 “(II) compare the number of
20 shipments under the regulations
21 under subsection (b) during the study
22 period that are determined to be
23 counterfeit, misbranded, or adulter-
24 ated, and compare that number with
25 the number of shipments made during

1 the study period within the United
2 States that are determined to be
3 counterfeit, misbranded, or adulter-
4 ated; and

5 “(III) consult with the Secretary,
6 the United States Trade Representa-
7 tive, and the Commissioner of Patents
8 and Trademarks to evaluate the effect
9 of importations under the regulations
10 under subsection (b) on trade and
11 patent rights under Federal law.

12 “(B) REPORT.—Not later than 2 years
13 after the effective date of the regulations under
14 subsection (b), the Institute of Medicine shall
15 submit to Congress a report describing the find-
16 ings of the study under subparagraph (A).

17 “(2) BY THE COMPTROLLER GENERAL.—

18 “(A) STUDY.—The Comptroller General of
19 the United States shall conduct a study to de-
20 termine the effect of this section on the price of
21 prescription drugs sold to consumers at retail.

22 “(B) REPORT.—Not later than 18 months
23 after the effective date of the regulations under
24 subsection (b), the Comptroller General of the
25 United States shall submit to Congress a report

1 describing the findings of the study under sub-
2 paragraph (A).

3 “(m) CONSTRUCTION.—Nothing in this section limits
4 the authority of the Secretary relating to the importation
5 of prescription drugs, other than with respect to section
6 801(d)(1) as provided in this section.

7 “(n) AUTHORIZATION OF APPROPRIATIONS.—There
8 are authorized to be appropriated such sums as are nec-
9 essary to carry out this section.”.

10 (b) CONFORMING AMENDMENTS.—The Federal
11 Food, Drug, and Cosmetic Act is amended—

12 (1) in section 301(aa) (21 U.S.C. 331(aa)), by
13 striking “covered product in violation of section
14 804” and inserting “prescription drug in violation of
15 section 804”; and

16 (2) in section 303(a)(6) (21 U.S.C. 333(a)(6)),
17 by striking “covered product pursuant to section
18 804(a)” and inserting “prescription drug under sec-
19 tion 804(b)”.

20 **SEC. 208. PEDIATRIC LABELING OF DRUGS AND BIOLOGI-**
21 **CAL PRODUCTS.**

22 (a) IN GENERAL.—Subchapter A of chapter V of the
23 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351
24 et seq.) is amended by inserting after section 505A the
25 following:

1 **“SEC. 505B. PEDIATRIC LABELING OF DRUGS AND BIOLOGI-**
2 **CAL PRODUCTS.**

3 “(a) NEW DRUGS AND BIOLOGICAL PRODUCTS.—

4 “(1) IN GENERAL.—A person that submits an
5 application (or supplement to an application)—

6 “(A) under section 505 for a new active in-
7 gredient, new indication, new dosage form, new
8 dosing regimen, or new route of administration;
9 or

10 “(B) under section 351 of the Public
11 Health Service Act (42 U.S.C. 262) for a new
12 active ingredient, new indication, new dosage
13 form, new dosing regimen, or new route of ad-
14 ministration;

15 shall submit with the application the assessments de-
16 scribed in paragraph (2).

17 “(2) ASSESSMENTS.—

18 “(A) IN GENERAL.—The assessments re-
19 ferred to in paragraph (1) shall contain data,
20 gathered using appropriate formulations, that
21 are adequate—

22 “(i) to assess the safety and effective-
23 ness of the drug, or the biological product
24 licensed under section 351 of the Public
25 Health Service Act (42 U.S.C. 262), for

1 the claimed indications in all relevant pedi-
2 atric subpopulations; and

3 “(ii) to support dosing and adminis-
4 tration for each pediatric subpopulation for
5 which the drug, or the biological product li-
6 censed under section 351 of the Public
7 Health Service Act (42 U.S.C. 262), is
8 safe and effective.

9 “(B) SIMILAR COURSE OF DISEASE OR
10 SIMILAR EFFECT OF DRUG OR BIOLOGICAL
11 PRODUCT.—If the course of the disease and the
12 effects of the drug are sufficiently similar in
13 adults and pediatric patients, the Secretary may
14 conclude that pediatric effectiveness can be ex-
15 trapolated from adequate and well-controlled
16 studies in adults, usually supplemented with
17 other information obtained in pediatric patients,
18 such as pharmacokinetic studies.

19 “(3) DEFERRAL.—On the initiative of the Sec-
20 retary or at the request of the applicant, the Sec-
21 retary may defer submission of some or all assess-
22 ments required under paragraph (1) until a specified
23 date after approval of the drug or issuance of the li-
24 cense for a biological product if—

25 “(A) the Secretary finds that—

1 “(i) the drug or biological product is
2 ready for approval for use in adults before
3 pediatric studies are complete; or

4 “(ii) pediatric studies should be de-
5 layed until additional safety or effective-
6 ness data have been collected; and

7 “(B) the applicant submits to the Sec-
8 retary—

9 “(i) a certified description of the
10 planned or ongoing studies; and

11 “(ii) evidence that the studies are
12 being conducted or will be conducted with
13 due diligence.

14 “(4) WAIVERS.—

15 “(A) FULL WAIVER.—At the request of an
16 applicant, the Secretary shall grant a full waiv-
17 er, as appropriate, of the requirement to submit
18 assessments under this subsection if—

19 “(i) necessary studies are impossible
20 or highly impractical;

21 “(ii) there is evidence strongly sug-
22 gesting that the drug or biological product
23 would be ineffective or unsafe in all pedi-
24 atric age groups; or

25 “(iii) the drug or biological product—

1 “(I) does not represent a mean-
2 ingful therapeutic benefit over existing
3 therapies for pediatric patients; and

4 “(II) is not likely to be used in a
5 substantial number of pediatric pa-
6 tients.

7 “(B) PARTIAL WAIVER.—At the request of
8 an applicant, the Secretary shall grant a partial
9 waiver, as appropriate, of the requirement to
10 submit assessments under this subsection with
11 respect to a specific pediatric age group if—

12 “(i) necessary studies are impossible
13 or highly impractical;

14 “(ii) there is evidence strongly sug-
15 gesting that the drug or biological product
16 would be ineffective or unsafe in that age
17 group;

18 “(iii) the drug or biological product—

19 “(I) does not represent a mean-
20 ingful therapeutic benefit over existing
21 therapies for pediatric patients in that
22 age group; and

23 “(II) is not likely to be used in a
24 substantial number of pediatric pa-
25 tients in that age group; or

1 “(iv) the applicant demonstrates that
2 reasonable attempts to produce a pediatric
3 formulation necessary for that age group
4 have failed.

5 “(C) LABELING REQUIREMENT.—If the
6 Secretary grants a full or partial waiver because
7 there is evidence that a drug or biological prod-
8 uct would be ineffective or unsafe in pediatric
9 populations, the information shall be included
10 in the labeling for the drug or biological prod-
11 uct.

12 “(b) MARKETED DRUGS AND BIOLOGICAL PROD-
13 UCTS.—

14 “(1) IN GENERAL.—After providing notice and
15 an opportunity for written response and a meeting,
16 which may include an advisory committee meeting,
17 the Secretary may by order require the holder of an
18 approved application relating to a drug under sec-
19 tion 505 or the holder of a license for a biological
20 product under section 351 of the Public Health
21 Service Act (42 U.S.C. 262) to submit by a specified
22 date the assessments described in subsection (a) if
23 the Secretary finds that—

1 “(A)(i) the drug or biological product is
2 used for a substantial number of pediatric pa-
3 tients for the labeled indications; and

4 “(ii) the absence of adequate labeling could
5 pose significant risks to pediatric patients; or

6 “(B)(i) there is reason to believe that the
7 drug or biological product would represent a
8 meaningful therapeutic benefit over existing
9 therapies for pediatric patients for 1 or more of
10 the claimed indications; and

11 “(ii) the absence of adequate labeling could
12 pose significant risks to pediatric patients.

13 “(2) WAIVERS.—

14 “(A) FULL WAIVER.—At the request of an
15 applicant, the Secretary shall grant a full waiv-
16 er, as appropriate, of the requirement to submit
17 assessments under this subsection if—

18 “(i) necessary studies are impossible
19 or highly impractical; or

20 “(ii) there is evidence strongly sug-
21 gesting that the drug or biological product
22 would be ineffective or unsafe in all pedi-
23 atric age groups.

24 “(B) PARTIAL WAIVER.—At the request of
25 an applicant, the Secretary shall grant a partial

1 waiver, as appropriate, of the requirement to
2 submit assessments under this subsection with
3 respect to a specific pediatric age group if—

4 “(i) necessary studies are impossible
5 or highly impractical;

6 “(ii) there is evidence strongly sug-
7 gesting that the drug or biological product
8 would be ineffective or unsafe in that age
9 group;

10 “(iii)(I) the drug or biological product
11 does not represent a meaningful thera-
12 peutic benefit over existing therapies for
13 pediatric patients in that age group;

14 “(II) the drug or biological product is
15 not likely to be used in a substantial num-
16 ber of pediatric patients in that age group;
17 and

18 “(III) the absence of adequate label-
19 ing could not pose significant risks to pedi-
20 atric patients; or

21 “(iv) the applicant demonstrates that
22 reasonable attempts to produce a pediatric
23 formulation necessary for that age group
24 have failed.

1 “(C) LABELING REQUIREMENT.—If the
2 Secretary grants a full or partial waiver because
3 there is evidence that a drug or biological prod-
4 uct would be ineffective or unsafe in pediatric
5 populations, the information shall be included
6 in the labeling for the drug or biological prod-
7 uct.

8 “(3) RELATIONSHIP TO OTHER PEDIATRIC PRO-
9 VISIONS.—

10 “(A) NO ASSESSMENT WITHOUT WRITTEN
11 REQUEST.—No assessment may be required
12 under paragraph (1) for a drug subject to an
13 approved application under section 505 un-
14 less—

15 “(i) the Secretary has issued a written
16 request for related pediatric studies under
17 section 505A(d) or section 409I of the
18 Public Health Service Act; and

19 “(ii)(I) if the request was made under
20 section 505A(d)—

21 “(aa) the recipient of the written
22 request does not agree to the request;
23 or

1 “(bb) the Secretary does not re-
 2 ceive a response as specified under
 3 section 505A(d)(4)(A); or

4 “(II) if the request was made under
 5 section 409I of the Public Health Service
 6 Act—

7 “(aa) the recipient of the written
 8 request does not agree to the request;
 9 or

10 “(bb) the Secretary does not re-
 11 ceive a response as specified under
 12 section 409I(c)(2) of that Act.

13 “(B) NO EFFECT ON OTHER AUTHOR-
 14 ITY.—Nothing in this subsection shall be con-
 15 strued to alter any requirement under section
 16 505A(d)(4) or section 409I of the Public
 17 Health Service Act. Subject to paragraph
 18 (2)(A), nothing in this subsection, section
 19 505A(d)(4), or section 409I or 499 of the Pub-
 20 lic Health Service Act shall be construed to pre-
 21 clude the Secretary from exercising the author-
 22 ity of the Secretary under this subsection.

23 “(c) FAILURE TO SUBMIT ASSESSMENTS.—If a per-
 24 son fails to submit a supplemental application containing
 25 the information or request for approval of a pediatric for-

1 mulation described in subsection (a) or (b) within the time
2 specified by the Secretary, the drug or biological product
3 may be considered by the Secretary to be misbranded and
4 subject to enforcement actions accordingly (except that
5 the drug or biological product shall not be subject to ac-
6 tion under section 303), and the failure shall not be the
7 basis for a proceeding to withdraw approval for a drug
8 under section 505(e) or revoke the license for a biological
9 product under section 351 of the Public Health Service
10 Act (42 U.S.C. 262).

11 “(d) MEETINGS.—The Secretary shall meet at appro-
12 priate times in the investigational new drug process with
13 the sponsor to discuss background information that the
14 sponsor shall submit on plans and timelines for pediatric
15 studies, or any planned request for waiver or deferral of
16 pediatric studies.

17 (b) CONFORMING AMENDMENTS.—

18 (1) Section 505(b)(1) of the Federal Food,
19 Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)) is
20 amended in the second sentence—

21 (A) by striking “and (F)” and inserting
22 “(F)”; and

23 (B) by striking the period at the end and
24 inserting “, and (G) any assessments required
25 under section 505B.”.

(2) Section 505A(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a(h)) is amended—

(A) in the subsection heading, by striking “REGULATIONS” and inserting “PEDIATRIC STUDY REQUIREMENTS”; and

(B) by striking “pursuant to regulations promulgated by the Secretary” and inserting “by a provision of law (including a regulation) other than this section”.

(3) Section 351(a)(2) of the Public Health Service Act (42 U.S.C. 262(a)(2)) is amended—

(A) by redesignating subparagraph (B) as subparagraph (C); and

(B) by inserting after subparagraph (A) the following:

“(B) PEDIATRIC STUDIES.—A person that submits an application for a license under this paragraph shall submit to the Secretary as part of the application any assessments required under section 505B of the Federal Food, Drug, and Cosmetic Act.”.

(c) FINAL RULE.—Except to the extent that the final rule is inconsistent with the amendment made by subsection (a), the final rule promulgating regulations requiring manufacturers to assess the safety and effectiveness

1 of new drugs and biological products in pediatric patients
2 (63 Fed. Reg. 66632 (December 2, 1998)), shall be con-
3 sidered to implement the amendment made by subsection
4 (a).

5 (d) NO EFFECT ON AUTHORITY.—Section 505B of
6 the Federal Food, Drug, and Cosmetic Act (as added by
7 subsection (a)) does not affect whatever existing authority
8 the Secretary of Health and Human Services has to re-
9 quire pediatric assessments regarding the safety and effi-
10 cacy of drugs and biological products in addition to the
11 assessments required under that section. The authority,
12 if any, of the Secretary of Health and Human Services
13 regarding specific populations other than the pediatric
14 population shall be exercised in accordance with the Fed-
15 eral Food, Drug, and Cosmetic Act (21 U.S.C. 301 et
16 seq.) as in effect on the day before the date of enactment
17 of this Act.

18 (e) TECHNICAL CORRECTION.—Section 505A of the
19 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a)
20 is amended in subparagraphs (A) and (B) of subsection
21 (b)(2) and subparagraphs (A) and (B) of subsection (c)(2)
22 by striking “505(j)(4)(B)” and inserting “505(j)(5)(B)”.

23 **SEC. 209. REPORT.**

24 (a) IN GENERAL.—Not later than the date that is
25 5 years after the date of enactment of this Act, the Fed-

1 eral Trade Commission shall submit to Congress a report
 2 describing the extent to which implementation of the
 3 amendments made by this title—

4 (1) has enabled products to come to market in
 5 a fair and expeditious manner, consistent with the
 6 rights of patent owners under intellectual property
 7 law; and

8 (2) has promoted lower prices of drugs and
 9 greater access to drugs through price competition.

10 (b) **AUTHORIZATION OF APPROPRIATIONS.**—There is
 11 authorized to be appropriated to carry out this section
 12 \$5,000,000.

13 **SEC. 210. CONFORMING AND TECHNICAL AMENDMENTS.**

14 (a) **SECTION 505.**—Section 505 of the Federal Food,
 15 Drug, and Cosmetic Act (21 U.S.C. 355) is amended—

16 (1) in subsection (a), by striking “(a) No per-
 17 son” and inserting “(a) **IN GENERAL.**—No person”;

18 (2) in subsection (b)—

19 (A) by striking “(b)(1) Any person” and
 20 inserting the following:

21 “(b) **APPLICATIONS.**—

22 “(1) **REQUIREMENTS.**—

23 “(A) **IN GENERAL.**—Any person”;

24 (B) in paragraph (1)—

25 (i) in the second sentence—

1 (I) by redesignating subpara-
 2 graphs (A) through (F) as clauses (i)
 3 through (vi), respectively, and adjust-
 4 ing the margins appropriately;

5 (II) by striking “Such persons”
 6 and inserting the following:

7 “(B) INFORMATION TO BE SUBMITTED
 8 WITH APPLICATION.—A person that submits an
 9 application under subparagraph (A)”;

10 (III) by striking “application”
 11 and inserting “application—”;

12 (ii) by striking the third through fifth
 13 sentences; and

14 (iii) in the sixth sentence—

15 (I) by striking “The Secretary”
 16 and inserting the following:

17 “(C) GUIDANCE.—The Secretary”; and

18 (II) by striking “clause (A)” and
 19 inserting “subparagraph (B)(i)”; and
 20 (C) in paragraph (2)—

21 (i) by striking “clause (A) of such
 22 paragraph” and inserting “paragraph
 23 (1)(B)(i)”;

24 (ii) in subparagraphs (A) and (B), by
 25 striking “paragraph (1) or”; and

1 (iii) in subparagraph (B)—

2 (I) by striking “paragraph
3 (1)(A)” and inserting “paragraph
4 (1)(B)(i)”; and

5 (II) by striking “patent” each
6 place it appears and inserting
7 “claim”;

8 (3) in subsection (c)—

9 (A) in paragraph (3)—

10 (i) in subparagraph (A)—

11 (I) by striking “(A) If the appli-
12 cant” and inserting the following:

13 “(A) **CLAUSE (i) OR (ii) CERTIFICATION.—**
14 If the applicant”; and

15 (II) by striking “may” and in-
16 serting “shall”;

17 (ii) in subparagraph (B)—

18 (I) by striking “(B) If the appli-
19 cant” and inserting the following:

20 “(B) **CLAUSE (iii) CERTIFICATION.—**If the
21 applicant”; and

22 (II) by striking “may” and in-
23 serting “shall”;

24 (iii) by redesignating subparagraph

25 (D) as subparagraph (E); and

- 1 (iv) in subparagraph (E) (as redesignated by clause (iii)), by striking “clause
- 2 (A) of subsection (b)(1)” each place it appears and inserting “subsection
- 3 (b)(1)(B)(i)”; and
- 4 (B) by redesignating paragraph (4) as
- 5 paragraph (5); and
- 6 (4) in subsection (j)—
- 7 (A) in paragraph (2)(A)—
- 8 (i) in clause (vi), by striking “clauses
- 9 (B) through ((F))” and inserting “sub-
- 10 clauses (ii) through (vi) of subsection
- 11 (b)(1)”; and
- 12 (ii) in clause (vii), by striking “(b
- 13 or”; and
- 14 (iii) in clause (viii)—
- 15 (I) by striking “(b) or”; and
- 16 (II) by striking “patent” each
- 17 place it appears and inserting
- 18 “claim”; and
- 19 (B) in paragraph (5)—
- 20 (i) in subparagraph (B)—
- 21 (I) in clause (i)—
- 22
- 23

1 (aa) by striking “(i) If the
2 applicant” and inserting the fol-
3 lowing:

4 “(i) SUBCLAUSE (I) OR (II) CERTIFI-
5 CATION.—If the applicant”; and

6 (bb) by striking “may” and
7 inserting “shall”;
8 (II) in clause (ii)—

9 (aa) by striking “(ii) If the
10 applicant” and inserting the fol-
11 lowing:

12 “(i) SUBCLAUSE (III) CERTIFI-
13 CATION.—If the applicant”; and

14 (bb) by striking “may” and
15 inserting “shall”;

16 (III) in clause (iii), by striking
17 “(2)(B)(i)” each place it appears and
18 inserting “(2)(B)”; and

19 (IV) in clause (v) (as redesign-
20 nated by section 4(a)(1)(B)), by strik-
21 ing “continuing” and inserting “con-
22 taining”; and

23 (ii) by redesignating subparagraphs
24 (C) and (D) as subparagraphs (E) and
25 (F), respectively.

1 (b) SECTION 505A.—Section 505A of the Federal
 2 Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is
 3 amended—

4 (1) in subsections (b)(1)(A)(i) and
 5 (c)(1)(A)(i)—

6 (A) by striking “(c)(3)(D)(ii)” each place
 7 it appears and inserting “(c)(3)(E)(ii)”; and

8 (B) by striking “(j)(5)(D)(ii)” each place
 9 it appears and inserting “(j)(5)(F)(ii)”; and

10 (2) in subsections (b)(1)(A)(ii) and
 11 (c)(1)(A)(ii)—

12 (A) by striking “(c)(3)(D)” each place it
 13 appears and inserting “(c)(3)(E)”; and

14 (B) by striking “(j)(5)(D)” each place it
 15 appears and inserting “(j)(5)(F)”; and

16 (3) in subsections (e) and (l)—

17 (A) by striking “505(c)(3)(D)” each place
 18 it appears and inserting “505(c)(3)(E)”; and

19 (B) by striking “505(j)(5)(D)” each place
 20 it appears and inserting “505(j)(5)(F)”; and

21 (4) in subsection (k), by striking
 22 “505(j)(5)(B)(iv)” and inserting “505(j)(5)(B)(v)”.

23 (c) SECTION 527.—Section 527(a) of the Federal
 24 Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)) is

- 1 amended in the second sentence by striking “505(c)(2)”
- 2 and inserting “505(c)(1)(B)”.

